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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HEALTHCOR OFFSHORE MASTER FUND, L.P., HEALTHCOR SANATATE OFFSHORE MASTER FUND, L.P., BLACKSTONE ALTERNATIVE MULTI-STRATEGY SUB FUND IV L.L.C., and BLACKSTONE ALTERNATIVE INVESTMENT FUND PLC, Plaintiffs, v. CELGENE CORPORATION, SCOTT A. SMITH, TERRIE CURRAN, and PHILIPPE MARTIN, Defendants.	Case No.: _____ **JURY TRIAL DEMANDED** **COMPLAINT AND JURY DEMAND**

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Plaintiffs Healthcor Offshore Master Fund, L.P., Healthcor Sanatate Offshore Master Fund, L.P., Blackstone Alternative Multi-Strategy Sub Fund IV L.L.C., and Blackstone Alternative Investment Fund PLC (collectively, "Plaintiffs") are purchasers of common stock issued by Celgene Corporation ("Celgene," or the "Company"). Plaintiffs, through their undersigned attorneys, by way of this Complaint and Jury Demand, for their federal securities and common law claims against Celgene and its former executive officers Scott A. Smith, Terrie Curran, and Philippe Martin (the "Individual Defendants," and, collectively with Celgene, the "Defendants"), allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters.[1]

Plaintiffs' information and belief is based on, *inter alia*, an investigation by their attorneys, which investigation includes, among other things, a review and analysis of: Celgene's filings with the United States Securities and Exchange Commission ("SEC"); public documents and media reports concerning Celgene; analyst reports concerning Celgene; transcripts of conference calls, earnings calls, and public presentations involving Defendants; pleadings, motion papers, and exhibits to declarations filed in the matter *In re Celgene Corporation Securities Litigation*, No. 18-cv-4772 (JMV) (the "Class Action"), including the Third Amended Consolidated Class Action Complaint ("Class Action Complaint") (ECF No. 178-1), the Court's December 19, 2019 Opinion (the "Class Action Motion to Dismiss Decision"), and the Court's November 29, 2020 Opinion ("Class Action Certification Decision"); and pleadings, motion papers, and exhibits to declarations filed in the matter *Schwab Capital Trust v. Celgene Corporation*, No. 20-cv-3754 (JMV), and the

[1] L. Civ. R. 10.1 Statement: Plaintiffs are investment funds whose investment advisor's principal place of business is 55 Hudson Yards, 28th Floor, New York, NY 10001. Defendant Celgene's principal place of business is 86 Morris Avenue, Summit, NJ 07901. The address of Individual Defendants Smith, Curran, and Martin is c/o Celgene Corporation, 86 Morris Avenue, Summit, NJ 07901.

Court's March 22, 2021 Opinion in that action ("Schwab Motion to Dismiss Decision"). Many of the facts supporting the allegations contained herein are known only to Defendants or are exclusively within their custody and/or control. As confirmed by the information made public in the Class Action Complaint that was obtained through discovery of Defendants, Plaintiffs believe that further substantial evidentiary support will exist for the allegations in this Complaint after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is an action to recover significant investment losses suffered as a result of a fraud perpetrated by Defendants.

2. Unbeknownst to Plaintiffs and the rest of the market, in 2017 and 2018, Defendants made material misrepresentations in order to artificially inflate the price of Celgene's common stock.

3. During the relevant time period, Celgene was a biopharmaceutical company that primarily developed and commercialized drugs for the treatment of cancer and inflammatory diseases.

4. A patent on a drug is akin to a government-enforced monopoly, excluding generic competitors from the market and allowing the drug maker to reap profits from being the exclusive seller of the drug. Celgene's flagship drug, Revlimid, a treatment for multiple myeloma (a type of blood cancer), was patented and was a blockbuster. Revlimid generated the majority of Celgene's revenue from 2013 through 2016:

Year	Total Net Sales	Revlimid Net Sales	% of Sales from Revlimid
2013	$6.36 billion	$4.28 billion	67.2%
2014	$7.56 billion	$4.98 billion	65.9%
2015	$9.16 billion	$5.80 billion	63.3%
2016	$11.18 billion	$6.97 billion	62.3%

5. But when a drug patent expires, generic competitors enter the market, eroding the market share for the formerly patented drug. Indeed, the Food and Drug Administration ("FDA") estimates that the price of a prescription drug drops by nearly 40% when a single generic competitor enters the market, 54% when two generic competitors enter the market, and more than 95% when six or more competitors enter the market.

6. This is what was going to happen to Revlimid, despite Celgene attempting to protect its exclusivity for the drug through at least 52 different patents. Although it had no generic competition since it came on the market in 2005, Revlimid was scheduled to lose patent exclusivity in 2022. Celgene knew that when Revlimid went off-patent, the Company could no longer count on the drug to provide billions of dollars in net sales that increased year after year.

7. Celgene needed a replacement for its blockbuster drug that could provide it with the revenue and sales growth of Revlimid. The fraud in this case concerns fraudulent misrepresentations by Defendants in 2016 through 2018 that two drugs in Celgene's Inflammation & Immunology franchise ("I&I"), Otezla and Ozanimod, were going to be billion-dollar blockbusters and provide Celgene with much needed revenue to allay concerns about what would happen to the Company when Revlimid went off-patent. Unbeknownst to the investing public, including Plaintiffs, Defendants' statements about Otezla and Ozanimod were materially false and misleading.

8. Otezla is a pill treatment for psoriasis and psoriatic arthritis, which Celgene began to sell in 2014. Otezla was the first FDA-approved pill treatment for adults with active psoriatic arthritis.

9. Ozanimod was an in-development treatment for multiple sclerosis and ulcerative colitis. Celgene acquired Ozanimod in its acquisition of another pharmaceutical company, Receptos, Inc. ("Receptos") in July 2015.

10. Rather than tell the investing public, including Plaintiffs, the truth about Otezla and Ozanimod, Defendants concealed (i) the true state of affairs about Otezla, including disappointing sales and barriers to increased market share; and (ii) that Celgene was disregarding the advice of its own scientists and its primary regulator, the FDA, about the requirements for getting Ozanimod FDA approval in late 2017, thus all but ensuring that the agency would reject the application.

11. Contrary to Celgene's public statements, in October 2017, it reduced its revenue guidance for Otezla by over $250 million. In February 2018, the FDA issued a Refusal to File ("RTF") rejection of Celgene's New Drug Application ("NDA") for Ozanimod. These events directly caused millions of dollars of losses to Plaintiffs when Celgene's stock-price declined, and served to correct Defendants' prior fraudulent statements and/or resulted from a materialization of the risks concealed by those fraudulent statements.

JURISDICTION AND VENUE

12. The claims asserted herein arise under and pursuant to Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, and under state common law.

13. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331, and has supplemental jurisdiction over the state law claim pursuant to 28 U.S.C. § 1367(a).

14. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391. Many of the acts giving rise to the violations complained of herein, including the

dissemination of false and misleading information, occurred in this District. In addition, the Class Action is pending in this District.

15. In connection with the acts, transactions and conduct alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone and wire communications and the facilities of a national securities exchange and market.

PARTIES

I. Plaintiffs

16. Plaintiff Healthcor Offshore Master Fund, L.P. is a Cayman Islands exempted limited partnership. Healthcor Offshore Master Fund, L.P. purchased or acquired Celgene common stock at artificially inflated prices on or after October 26, 2016 (for its common law fraud claim) and on or after April 27, 2017 (for its Exchange Act claim) and held Celgene common stock through and after April 30, 2018, when the last in a series of partial but inadequate disclosures was issued correcting the prior materially false and misleading statements and as the foreseeable risks concealed by Defendants' material misstatements and omissions partially materialized.

17. Healthcor Sanatate Offshore Master Fund, L.P. is a Cayman Islands exempted limited partnership. Healthcor Sanatate Offshore Master Fund, L.P. purchased or acquired Celgene common stock at artificially inflated prices on or after October 26, 2016 (for its common law fraud claim) and on or after April 27, 2017 (for its Exchange Act claim) and held Celgene common stock through and after April 30, 2018, when the last in a series of partial but inadequate disclosures was issued correcting the prior materially false and misleading statements and as the foreseeable risks concealed by Defendants' material misstatements and omissions partially materialized.

18. Blackstone Alternative Multi-Strategy Sub Fund IV L.L.C. is a Delaware limited liability company. Blackstone Alternative Multi-Strategy Sub Fund IV L.L.C. purchased or acquired Celgene common stock at artificially inflated prices on or after October 26, 2016 (for its common law fraud claim) and on or after May 31, 2017 (for its Exchange Act claim) and held Celgene common stock through and after April 30, 2018, when the last in a series of partial but inadequate disclosures was issued correcting the prior materially false and misleading statements and as the foreseeable risks concealed by Defendants' material misstatements and omissions partially materialized.

19. Blackstone Alternative Investment Fund PLC is an Irish-domiciled UCITS. Blackstone Alternative Investment Fund PLC purchased or acquired Celgene common stock at artificially inflated prices on or after October 26, 2016 (for its common law fraud claim) and on or after May 31, 2017 (for its Exchange Act claim) and held Celgene common stock through and after April 30, 2018, when the last in a series of partial but inadequate disclosures was issued correcting the prior materially false and misleading statements and as the foreseeable risks concealed by Defendants' material misstatements and omissions partially materialized.

20. At all relevant times, HealthCor Management, L.P. ("HealthCor") acted as investment adviser or subadviser to Plaintiffs in connection with their purchases of Celgene securities.

II. Defendants

21. During the relevant time period, Defendant Celgene was a Delaware corporation headquartered in Summit, New Jersey. Celgene was a biopharmaceutical company that primarily developed and commercialized drugs for the treatment of cancer and inflammatory diseases. Two of the Company's operating divisions, known as franchises, are relevant to this action: the Hematology and Oncology franchise, which develops drugs to treat cancer and blood disease; and

the I&I franchise, which develops drugs to treat inflammatory diseases, including psoriasis, psoriatic arthritis, ulcerative colitis, multiple sclerosis, and Crohn's disease. During the relevant time period, Celgene's common stock traded on the NASDAQ.

22. Defendant Smith served as Celgene's President and Chief Operating Officer from April 1, 2017 through April 2, 2018, when he abruptly resigned. Before his role as COO, Smith was President of I&I. As COO, Celgene represented that Smith was "fully engaged in company-wide strategic planning and decision-making aimed at ensuring [the Company's] long-term success through delivering on annual and long-term financial goals and through continuing to innovate, develop and commercialize life-changing drugs for . . . patients." Smith was a member of Celgene's Inflammation and Immunology Executive Committee ("IIEC"). Based on discovery obtained from Defendants, the Class Action Plaintiffs allege that Smith, as both COO and President of I&I, actively participated in Celgene's process for preparing and making public disclosures to the market regarding the Company's financial performance and clinical development matters, including, in each fiscal quarter from at least 2016 through April 2, 2018, serving as a core participant in the senior executive team that prepared, drafted, reviewed, and finalized: (i) Celgene's quarterly earnings call and Q&A script; (ii) the investor slide deck presentation that Celgene published on its website to accompany each quarterly earnings release; (iii) the press releases that Celgene published along with each quarterly earnings release and upon other important events; and (iv) the SEC Forms 10-Q or 10-K that Celgene filed and published for each fiscal period.

23. Defendant Curran became President of Celgene's Global I&I franchise on April 1, 2017, and remained in this role throughout the relevant period. Prior to that role, Curran was Head of Worldwide Markets for I&I from March 2016 through April 1, 2017. Curran had previously

been the U.S. Commercial Head of I&I from April 2013 through March 2016. On September 27, 2019, Phathom Pharmaceuticals ("Phathom") announced that it had hired Curran as CEO. In its press release, Phathom stated that Curran had been responsible for the "launch . . . of OTEZLA" and had "built the capabilities and recruited the teams that executed the . . . launch of OTEZLA." Curran was a member of the IIEC. Based on discovery obtained from Defendants, the Class Action Plaintiffs allege that as President of I&I, Curran actively participated in Celgene's process for preparing and making public disclosures to the market regarding financial performance and clinical development matters of I&I. In particular, in each fiscal quarter during her tenure as President of I&I, Curran was a core participant in the senior executive team that prepared, drafted, reviewed, revised and finalized: (i) Celgene's quarterly earnings call and Q&A script; (ii) the investor slide deck presentation that Celgene published on its website to accompany each quarterly earnings release; (iii) the press releases that Celgene published along with each quarterly earnings release and upon other important events; and (iv) the SEC Forms 10-Q or 10-K that Celgene filed and published for each fiscal period. As President of I&I, Curran had particular responsibilities with respect to providing and reviewing language in Celgene's earnings call scripts, investor slide decks, press releases and SEC Forms 10-Q and 10-K that discussed clinical development matters within I&I and the financial performance of I&I products.

24. Defendant Martin was Celgene's Vice President of Leadership & Project Management – Immunology from January 2014 through early March 2018. Martin also served as Celgene's Corporate Vice President from January 2017 to March 2018. From June 2016 to March 2018, Martin was also Managing Director at Celgene-Receptos, and was the most senior employee at the Celgene-Receptos facility in San Diego, California. Martin was a member of the IIEC. Based on discovery obtained from Defendants, the Class Action Plaintiffs allege that Martin's

responsibilities for the Ozanimod NDA were to (i) to ensure the development of Ozanimod and to monitor the Ozanimod NDA team's progress toward the completion of the NDA submission, (ii) to ensure that the IIEC was apprised of what the project teams at Receptos were working on, including the Ozanimod NDA team, and (iii) to ensure that Celgene was involved in the decision-making process with respect to the NDA submission. Martin provided updates regarding the Ozanimod NDA to the IIEC, including during its meetings, and, on a quarterly basis, to Celgene's Board of Directors.

III. Certain Relevant Celgene Employees

25. Jay T. Backstrom, M.D., was Celgene's Chief Medical Officer from 2017 to 2019, and reported to Defendant Smith.

26. Matthew Lamb was Celgene's Vice President and Global Head of Regulatory Affairs in I&I from April 2015 to November 2019 and reported to Backstrom.

27. Jean Louis Saillot, M.D., was Vice President of Project Leadership Regulatory Affairs, and Clinical Pharmacology at Receptos from November 2016 to November 2019. Saillot reported to Defendant Martin.

28. Maria Palmisano was Celgene's Vice President of Clinical Pharmacology at all relevant times.

29. Jonathan Tran was the Executive Director of Clinical Pharmacology at Receptos from July 2015 to November 2019, and reported to Saillot.

30. Esther Martinborough was the Executive Director of Research in Computational Chemistry at Receptos from 2015 to 2018. Martiborough reported to Defendant Martin.

31. Susan Meier-Davis, Ph.D. was the Senior Director in Pre-Clinical Sciences at Receptos from April 2016 to 2018, and reported to Martinborough.

32. David Kao was the Senior Director of Regulatory Affairs at Receptos from July 2015 to April 2016 and then Executive Director of Regulatory Affairs at Receptos from May 2016 to April 2020. In 2016 and 2017, Kao reported to Saillot. In 2018, Kao reported to Lamb.

33. Gerlee Thomas was the Director of Regulatory Affairs at Receptos from July 2016 to March 2018, and reported to Kao.

34. Richard Aranda was the Vice President of Clinical Development at Receptos from January 2015 to February 2018, and reported to Defendant Martin.

35. Brett E. Skolnick was Director of Clinical Development at Receptos during all relevant times, and reported to Aranda.

36. Ted Reiss was Celgene's Corporate Vice President and the Head of I&I Clinical Research and Development Management from September 2015 through 2018. Reiss reported to Defendant Curran in 2017.

37. Karen Zoller was the Senior Director of Project Management at Receptos from November 2014 to 2018. Zoller reported to Saillot.

38. Paul Frohna was Vice President of Clinical Development and Translational Medicine at Receptos from December 2013 to October 2016, and reported to Defendant Martin.

39. Jeffrey J. Kopicko was the Executive Director of Biometrics at Receptos from June 2016 to May 2017 and the Senior Director of Biostatics from July 2015 to June 2016. Kopicko reported to Saillot in 2016.

40. The Class Action Complaint alleges that according to a personnel matrix dated March 9, 2017, and received in discovery, the following individuals were responsible for and involved in authoring, reviewing, and approving, various sections of the Ozanimod NDA: (a) Martin; (b) Lamb; (c) Saillot; (d) Aranda, (e) Skolnick; (f) Reiss; (g) Tran; (h) Palmisano; (i)

Kopicko; (j) Kao; (k) Thomas; (l) Meier-Davis; (m) Martinborough; and (n) Zoller. In addition, as Celgene's Chief Medical Officer, Backstrom had the final authorization to submit the NDA on the Company's behalf.

41. Robert Tessarolo was Vice President and General Manager of I&I at Celgene from September 2015 to April 2017 and reported to Defendant Curran.

42. Betty Jean Swartz was a Vice President of U.S. Market Access at Celgene from April 2016 to January 2018, and reported to Tessarolo.

IV. Certain Relevant Former Celgene Employees, Consultants, and Scientists

43. In the Class Action, Plaintiffs plead, in part, facts originally based on information obtained from former Celgene employees, consultants, and scientists.

44. As it recognized in the Schwab Motion to Dismiss Decision, in in its Motion to Dismiss Decision in the Class Action, the Court held that "generally, the [former employees'] information was sufficient to support a properly-pled complaint."

45. In its Motion to Dismiss Decision in the Schwab Action, the Court held that it would "consider th[e] information" alleged by the Former Employees in the Class Action, where those allegations were reproduced in the Schwab Complaint.

46. Former employees, consultants, and scientists will be identified herein by the designation "FE," followed by a number. Plaintiffs use the same numbering herein as used by the Class Action Plaintiffs in the Third Amended Consolidated Class Action Complaint. (ECF No. 178-1.) As in that complaint, all FEs herein will be described in the masculine, regardless of gender.

47. FE 2 worked in Clinical Research & Development in I&I through late 2016 in Summit, New Jersey. FE 2's responsibilities included long-term planning of both organizational and project-related activities, and assisting the Vice President of the I&I Clinical Research and

Development department with the management of the department. FE 2 also participated in clinical development planning for I&I's compounds and managed department activities to ensure timely delivery of the clinical component of regulatory submissions.

48. FE 5 was employed as a Director at Receptos from mid-2015 to mid-2017. While at Receptos, FE 5 oversaw and performed statistical analyses for the Ozanimod Crohn's disease and ulcerative colitis studies. In this role, FE 5 was a regular attendee at meetings related to Celgene's Ozanimod clinical trials, including meetings regarding the submission of Ozanimod for FDA approval as a treatment for relapsing multiple sclerosis ("RMS"). While at Receptos, FE 5 reported to Kopicko, the Executive Director of Biometrics. Kopicko reported to Defendant Martin, who, in turn, reported to Defendant Smith.

49. FE 6 was a Regional Medical Liaison for I&I in the New England region from at least May 2015 to late 2017. In this role, FE 6 was part of the Market Access team, where he worked with Account Manager teams to identify scientific and medical support needs for accounts with marketed and pipeline I&I products. FE 6 was also responsible for maintaining a working knowledge of all I&I products so that he could educate the Account Managers on a product's clinical data.

50. FE 7 was a Senior National Account Manager at Celgene from 2013 to 2016. FE 7's work encompassed Market Access, in which he had 18 years of experience. FE 7 advised Celgene's senior executives on the pricing strategy and market access strategy for Otezla. These senior executives included Sal Grausso, Executive Director of Market Access for I&I, Swartz, Vice President of U.S. Market Access, Robert Tessarolo, Senior Vice President of I&I, U.S., Gordon Willcox, Vice President of Market Access, and Defendant Curran. In his role as Senior

National Account Manager, FE 7 reported to Defendant Curran and Grausso, who in turn reported to Defendant Smith.

51. FE 8 was an I&I Sales Representative at Celgene in the Northeast Region from at least May 2015 to late 2017. FE 8 focused on selling Otezla.

52. FE 9 was a Dermatology Specialty Sales Territory Manager at Celgene in the Southwest Region from at least May 2015 to early 2017. FE 9 focused on selling Otezla and was involved in the drug's launch.

53. FE 10 was a Rheumatoid Sales Specialist for Celgene from early 2015 to late 2016. FE 10 was responsible for Otezla sales in the Northeast Region.

54. FE 11 was a Celgene District Sales Manager for the Northeast Region from at least May 2015 to late 2016. In that role, FE 11 received weekly reports about Otezla sales volume and growth for the prior week, quarter, and half-year, and a year-over-year comparison. FE 11 also supervised eleven Otezla sales representatives: five rheumatoid representatives and six dermatology representatives.

55. FE 12 was a Sales Representative for Celgene from at least May 2015 to late 2017. FE 12 was responsible for Otezla sales in the Northeast Region.

56. FE 13 was a Regional Sales Manager at Celgene in early 2015. FE 13 was in charge of I&I sales for more than five states in the mid- and western United States. FE 13 was responsible for the launch and sales of Otezla.

57. FE 14 was a Sales Representative at Celgene from at least May 2015 to early 2017. FE 14 promoted Otezla to doctors in a large Northeast market, from the early days of Otezla's launch until he left Celgene. At least quarterly, FE 14 received a ranking report, which force ranked FE 14 against other Otezla sales personnel based on their volume of Otezla sales.

58. FE 15 was a senior member of the Pricing and Market Access group at Celgene from at least May 2015 to late 2015. In this role, FE 15 developed market access models for various drugs, including Otezla. These models were based on the drug's efficacy compared to other medications already in the market. FE 15 provided the models to Frank Zhang, Celgene's Global Head of HEOR, who reported to Defendant Smith.

59. FE 16 was a high-ranking member of HEOR and Pricing for the U.K. and Ireland at Celgene throughout the relevant time period. In this role, FE 16 was responsible for submitting reimbursements to the National Institute for Health and Care Excellence, the United Kingdom's executive non-departmental public body that determines whether the U.K. government will reimburse a company for a new drug. FE 16 reported to the Head of Market Access and Corporate Affairs for the U.K. and Ireland, the Global Head of HEOR and Pricing for I&I in the United States, who reported to Defendant Smith, and a high-ranking member of the Global Market Access group.

60. FE 17 was a senior executive in the U.S. Market Access group at Celgene from early 2016 to late 2017. In that role, FE 17 worked with the managed care team to negotiate new contracts with health plans. FE 17 led the U.S. Market Access team responsible for optimal patient access, strategic development, and execution of Celgene's value proposition. FE 17 also prepared pricing recommendations for the IIEC, which included pricing recommendations for Otezla. FE 17 reported to Tessarolo. Tessarolo, in turn, reported to Defendant Smith and Defendant Curran.

61. FE 18 was a senior executive in the U.S. Health Economics and Outcomes Research ("HEOR") group at Celgene from at least May 2015 to early 2018. FE 18 reported to Swartz.

62. FE 19 was a senior executive in U.S. Field HEOR from mid-2016 through the end of the relevant time period. FE 19 worked in external Market Access to guide key decision makers

with respect to patient access to specific drugs and services, efficacy, and safety. FE 19 ultimately reported to the Executive Director of U.S. HEOR.

63. FE 20 was a senior executive in Clinical Development at Receptos from at least May 2015 to late 2016. FE 20 was responsible for conducting all of the Phase II and Phase III studies for Ozanimod for multiple sclerosis and ulcerative colitis.

64. FE 21 was a Clinical Pharmacologist at Receptos from late 2016 to early 2018 and worked on the Phase I studies of Ozanimod. FE 21 contributed to the clinical pharmacology section of the Ozanimod NDA and had first-hand knowledge of the Metabolite starting at the time of its discovery. Following this discovery, FE 21 worked on studies regarding the Metabolite, including tests to identify and characterize the Metabolite.

65. FE 22 was a contractor for Receptos and worked as a Project Manager for the Ozanimod ulcerative colitis/Crohn's disease ("UC/CD") team in San Diego between late 2017 and early 2018. In that role, FE 22 oversaw the Ozanimod UC/CD drug development through various clinical stages, was also kept apprised of the status of the Ozanimod multiple sclerosis project.

FACTUAL ALLEGATIONS

I. Revlimid Is Celgene's Golden Goose, But Only Until 2022.

66. Revlimid is primarily used to treat multiple myeloma, a form of blood cancer, and is a pill that is taken orally.

67. Celgene took Revlimid to market in 2006, and the drug quickly became the Company's flagship product.

68. Revlimid fueled Celgene's profitability. The Company's net income grew nearly every year after launching the drug. In 2009, Celgene's net income was $780 million. By 2014, net income had grown to $2 billion. Revlimid delivered a majority of that income:

Year	Total Net Sales	Revlimid Net Sales	% of Sales from Revlimid
2013	$6.36 billion	$4.28 billion	67.2%
2014	$7.56 billion	$4.98 billion	65.9%
2015	$9.16 billion	$5.80 billion	63.3%
2016	$11.18 billion	$6.97 billion	62.3%

69. Revlimid was so popular that Celgene's former Senior Vice President of Sales and Marketing testified in a 2015 deposition that the Company could raise the drug's price "any time they wanted." Indeed, in 2005, when it launched, Revlimid was priced at $215 per pill, and the price had reached nearly $500 per pill by 2014.

70. Celgene used Revlimid to achieve its revenue targets and earnings goals. For example, on March 4, 2014, then-Executive President Mark Alles (who later become CEO) suggested a 4% price increase for Revlimid "not later than the end of next week and a second price increase of 3% on September 1st rather than October 1st," because he had "to consider every legitimate opportunity available . . . to improve . . . Q1 performance." An internal presentation estimated that the price increase would enhance net sales by almost $25 million. Similarly, Celgene raised the price on Revlimid by 6.8% in March 2016 and by another 3% in August of that year. An internal presentation estimated that those price increases would increase net sales by more than $217 million.

71. During this period, Revlimid was protected from generic competition by patents, meaning that Celgene could count on substantial and increasing revenue from the drug year after year. Indeed, Celgene went to great lengths to protect Revlimid's patent exclusivity.

72. Because of a risk of birth defects, Celgene was required by the FDA to implement a Risk Evaluation and Mitigation Strategy ("REMS") program for Revlimid. Celgene used its REMS program—which severely limits the distribution of Revlimid—to prevent generic

manufacturers from buying Revlimid samples. An internal Celgene presentation examining whether to adopt a REMS program for another drug stated that a benefit of the program was the "prevention of generic encroachment."

73. According to the FDA, Celgene used its REMS program to prevent or delay 14 potential generic competitors from obtaining samples of Revlimid. When Mylan Pharmaceuticals tried to buy Revlimid samples in 2013, Celgene cited its REMS program to delay. In 2014, the FDA told Celgene to "provide Mylan with sufficient quantity of REVLIMID to conduct necessary testing." Yet Celgene still refused, forcing Mylan to sue for access. The case settled in 2019, with Celgene paying Mylan $62 million.

74. Celgene also filed for ten separate patents on its Revlimid REMS program and enforced those patents against potential generic competitors. Two of the patents were later invalidated.

75. An internal Celgene presentation from 2016 stated that it could "shape the operating environment to support business goals" by "prevent[ing] legislative erosion of [its] REMS program."

76. Celgene also leveraged the patent system to obtain or apply for at least 52 patents on Revlimid. Eleven of these patents cover different chemical structures of Revlimid's active ingredient. The European Patent Office invalidated those patents in 2015, but they remained valid in the United States. The Initiative for Medicine, Access, and Knowledge estimates that the extended patent exclusivity of Revlimid due to Celgene's secondary patents will increase U.S. healthcare costs by $45 billion.

77. But Celgene had a problem. Revlimid's U.S. patent exclusivity expired in 2022. In addition, Celgene was under frequent attack from generic drug manufacturers seeking to

invalidate patents associated with Revlimid. Something had to be done to replace Revlimid's massive revenue contribution to Celgene before generic Revlimid competitors entered the marketplace.

II. GED-0301, a Costly Unsuccessful Drug.

78. Celgene attempted to augment its drug pipeline and revenue from GED-0301, a drug used to treat Crohn's Disease and ulcerative colitis. In April 2014, Celgene announced a deal with Nogra Pharma Limited for Celgene to develop GED-0301. Celgene paid $710 million and agreed to potential additional payments of up to almost $2 billion. The upfront fee was the largest ever for the acquisition of a single drug.

79. The promise of GED-0301 was that it was an oral medication, whereas the existing treatments for Crohn's disease and ulcerative colitis were injectable biologics. This provided Celgene with a path to break into the lucrative market for treating these conditions, with potentially billions of dollars in annual sales if successful.

80. But this did not happen. GED-0301 did not work. In October 2017, Celgene discontinued Phase III trials on the drug, which analysts recognized was the death-knell for GED-0301's prospects.

III. Celgene Heralds That Otezla Will Fill the Revlimid Revenue Gap

81. The second drug to potentially replace Revlimid was Otezla, which was the most commercially advanced drug in I&I's pipeline. Like GED-0301, Otezla, which treated psoriasis and psoriatic arthritis, was a pill attempting to break into a market dominated by injectable biologics.

82. Otezla was approved by the FDA in March 2014 to treat psoriatic arthritis. Even before this approval, Celgene was promising the market that Otezla sales would reach $1.5 to $2 billion per year by 2017.

83. On January 12, 2015, Celgene issued a press release containing the Company's 2017 and 2020 long-term financial targets. The press release stated that Celgene expected net product sales of Otezla of $1.5 to $2 billion in 2017.

84. While this was the story Celgene was telling the investing public, things were different inside the Company.

IV. From Its Launch, Otezla Faces Multiple Barriers To Increasing Sales

85. According to FE 7, a Senior National Account Manager, as early as Otezla's March 2014 launch, the drug's sales and revenue generating capabilities were severely impaired by several dynamics.

A. Celgene's Costly Rebate And Discount Strategy

86. As alleged in the Class Action, FE 7 stated that shortly after Otezla's launch, Celgene offered excessive rebates and discounts to persuade insurance companies to remove "step-edits," the requirements by insurers and pharmacy benefits mangers ("PBMs") that patients try other, less expensive treatments before being allowed to use Otezla. Although Celgene's goal was to increase Otezla's market share, FE 7 says that the plan had no chance of success.

87. Under the Medicaid Drug Rebate Program, manufacturers must report drug pricing information to the U.S. government. That information is used to calculate each drug's per-unit Medicaid rebate amount. Crucially, the rebate calculation takes into account the so-called "best price" of the drug, *i.e.*, the lowest price paid for the drug by any wholesaler, provider, retailer, HMO, government entity, nonprofit, or other health care purchaser. Thus, discounts and rebates provided to private insurance companies ultimately lower the price that Medicaid will pay for that drug. Medicaid was one of the largest purchasers of Otezla.

88. As alleged in the Class Action, FE 7 explained that the steep rebates and discounts on Otezla put downward pressure on sales revenues for the drug because of their impact on

Celgene's best-price calculation for Otezla. Thus, rather than increasing net sales through gaining additional market shares, Celgene ended up selling the drug for what FE 7 illustratively described as one cent per pill. This meant that Celgene would not meet its 2017 Otezla sales guidance.

89. According to FE 7, Defendant Smith made the ultimate decisions about Otezla and its market access strategy. Beginning in 2014, FE 7 repeatedly told Defendant Smith that the Otezla discount strategy would not increase revenue. When Otezla launched, FE 7 warned Defendant Smith that a rebate-and-discount strategy would lower the best price for Otezla and ultimately harm future net sales. Defendant Smith replied that Celgene would do "whatever it takes to get the business."

90. FE 7 also repeatedly emailed Celgene's executive management, including Defendant Smith, documenting his concerns about the rebate-and-discount strategy and that this approach would prevent the Company from maximizing profits. Celgene did not heed FE 7's advice.

B. Otezla Simply Doesn't Work As Well As Competitor Drugs

91. As alleged in the Class Action, FE 7 also stated that Otezla simply performed worse as a treatment than Amgen's Enbrel, the leading biologic treatment for psoriasis and psoriatic arthritis, and other competitor drugs. This would make market penetration and thus increasing Otezla revenue more difficult.

92. The Class Action Complaint includes numerous accounts about Otezla simply not being as effective as other available competitor drugs for treating psoriasis and psoriatic arthritis:

- FE 9 explained that Humira produced positive results more quickly than Otezla and was more effective for individuals who suffered only from psoriasis.
- FE 8 stated that Otezla's main competitors, Humira and Enbrel, were simply more effective products with broader indications than Otezla. Humira and Enbrel could be prescribed to patients with mild to severe symptoms and

typically worked within two to three weeks, whereas Otezla was only approved for mild to moderate indications and required up to four months to produce noticeable results. FE 8 referred to Otezla as "training wheels" compared to Humira and Enbrel.

- FE 11 stated that there was an increase in competitor products entering the market during the relevant time period, and in contrast to Otezla's efficacy rate of approximately 33%, these new biologic competitors had efficacy rates between 50% and 75%. As FE 11 explained, this made it difficult to convinced doctors and patients to switch to Otezla.

- FE 13 likewise confirmed that the efficacy of Otezla was nothing groundbreaking and not nearly as efficacious as some of the other competitors.

- FE 12 and FE 14 also indicated that there were issues with Otezla's efficacy and FE 12 specifically stated that Otezla worked slower than other competitor products and that these competitor products had more efficacy data. FE 12 further noted that there were significant deviations between patients in terms of Otezla's efficacy.

93. The number of well-accepted and established drugs for treating psoriasis and psoriatic arthritis already on the market also hampered Celgene's efforts to increase Otezla sales and gain market share. As recounted in the Class Action Complaint:

- FE 9 explained that the market for psoriasis and psoriatic arthritis medications was oversaturated with competitor treatments, including established drugs like Humira. Doctors had many choice and Otezla was not at the top of the list—other, better known treatments were.

- FE 8 stated Otezla had difficulty capturing market share from its main competitors, Enbrel and Humira, as they had been on the market since 2002 and 2005, respectively.

- FE 11 similarly recounted that Humira was the "big kid on the block" and was already entrenched in the Northeast Region.

- FE 13 indicated that the growth of Otezla sales was limited by Humira's successful saturation of the market.

- FE 13 explained that while Celgene wanted Otezla to be the first in-step therapy, in light of its safety profile, that was just a "pipe dream" because Methotrexate (another competitor) was so much cheaper and had been in use for so long that it just was never going to happen.

- According to FE 13, Otezla was always designed to be a niche product as compared to its previously launched competitors.

94. Making matters worse, FE 7 added that from launch, Defendant Smith hired inexperienced sales representatives to sell Otezla.

C. Widespread Knowledge Within Celgene of Otezla's Sales Problems

95. As alleged in the Class Action, FE 7's account was corroborated by former Celgene sales representatives from around the country. And they all said the same thing—that from 2015 through 2017, Otezla's sales growth was essentially flat because of the factors discussed above:

- FE 8, a Celgene Sales Representative in the Northeast Region, confirmed that his annual Otezla sales were flat from early 2014 through late 2017—the entire time he worked for Celgene.

- FE 9, a Sales Territory Manager in the Southwest Region, recounted that by 2015, the growth of his Otezla sales had flattened and stayed that way until he left Celgene in March 2017.

- FE 10, a Celgene Sales Representative in upstate New York, stated that, during his entire time with Celgene (from early 2015 until the end of 2016), it was "certainly a struggle to sell" Otezla, particularly on the rheumatology side—*i.e.*, for patients suffering from psoriatic arthritis. As FE 10 explained, "[o]nce the buzz [around Otezla] had dropped off by 2016, and once providers got a sense [Otezla] wasn't going to work that well," increasing sales of Otezla "started to become a huge issue." Thus, FE 10 recalls that "the consensus was that the growth was not sustainable by 2016."

- FE 11, a District Sales Manager for the Northeast Region, stated that by 2016, his Otezla sales had flattened and there was a decline in annual growth.

- FE 12, a Sales Representative in the Northeast Region, similarly noticed a slowing of Otezla sales, particularly around October 2016.

- FE 13, a Regional Sales Manager, said that it was virtually impossible for Celgene to sell enough Otezla to meet its 2017 guidance. Specifically, FE 13 stated that the idea that Otezla could ever achieve 40% year-over-year growth in net product sales in 2017, let alone the 57% growth Defendants projected in January 2017, was absurd. FE 13 explained that he had seen no indication that would justify that kind of projection unless Celgene was

> expecting some huge shift in the managed care environment, and that it makes no logical sense to see those numbers domestically.

96. The former sales representatives referred to in the Class Action Complaint also confirmed that Celgene executives had access to information demonstrating that the Company was unable to grow Otezla sales. FE 14 stated that Celgene management knew of Otezla's struggles because all of the sales results were available to management through a computer program called Tableau. FE 12 explained that Tableau is a computer data tool that Celgene used to compile and analyze sales data received from IMS, a company that collects pharmaceutical data. The Tableau data Otezla included straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. According to FE 12, anyone from the sales side at Celgene could log on to Tableau and view the Otezla sales data. The degree of access to the data increased as you went higher up in the Company.

97. As alleged in the Class Action, the former sales representatives also confirmed FE 7's account, uniformly attributing Otezla's sales issues to: (i) Otezla's inferior efficacy compared to its competitors, including the fact that it worked slower than other drugs and was only effective for certain indications; (ii) challenges with insurance coverage for Otezla, including step-edits and preauthorization requirements; and (iii) various other obstacles that made it difficult for patients to get Otezla or negatively impacted the ability of sales representatives to sell Otezla. These persistent and widespread roadblocks to increasing Otezla sales made Celgene's 2017 Otezla guidance unattainable. Thus, Defendants' representations reaffirming that guidance were materially false and misleading.

D. Insurance Company Rules Also Hamper Otezla Sales

98. Celgene also faced headwinds from insurance company rules in increasing Otezla sales from May 2015 through at least 2016, including requiring preauthorization to cover Otezla or step-edit programs that mandated another therapy before Otezla would be authorized. Almost 70% of insurance plans had step-edit programs generally in 2015. As recounted in the Class Action Complaint:

- FE 9 reported issues with insurance companies, including that preauthorization was routinely denied for Otezla and patients had to try other first-line drugs due to insurers' step-edit requirements. Insurance companies initially would not budge on coverage for Otezla.
- FE 14 stated that Otezla suffered from challenges with insurance coverage, including step-edits.
- FE 10 stated that insurance providers were unwilling for an initial period to reimburse patients for Otezla.
- FE 11 explained that several of the managed care groups in the Northeast Region had step-edits in place that required patients to use and reject Humira and Enbrel before they would approve Otezla, and the appeals process was cumbersome, so most doctors and plans opted to take the easier route by prescribing other drugs.

99. Adding to all of these issues surrounding Otezla sales, according to FE 9, because Otezla was a specialty drug, it had to be ordered from specialty pharmacies, unlike Humira and Enbrel, which could be picked up at regular pharmacies, such as CVS or a local independent pharmacy. This made it harder for patients to get Otezla, even if prescribed and covered by insurance. In addition, both FE 7 and FE 14 reported that Celgene's Otezla sales representatives were very inexperienced, which adversely impacted their ability to sell the drug.

E. Sales Difficulties in Europe, Too

100. The Class Action Complaint also includes accounts from former Celgene employees about the Company's difficulties in expanding Otezla sales in Europe.

101. FE 15, a senior member of the Pricing and Market Access group throughout 2015, was charged with creating pricing and market access models for reimbursement applications that Celgene submitted to foreign national healthcare organizations in conjunction with efforts to obtain approval to market Otezla in Europe. As FE 15 explained, during the relevant time period, there were two main hurdles before a drug could be marketed outside the United States: (i) the drug must be approved by the foreign counterpart to the FDA; and (ii) a reimbursement application must be accepted by the national healthcare organization charged with evaluating, among other things, the efficacy, cost, and potential patient base for a drug.

102. In developing the models for Celgene's reimbursement applications, FE 15 struggled with Otezla's lack of compelling efficacy data because the models are usually driven by a drug's efficacy compared to other medications that are already in the market space. As he explained: "Otezla is worse than other things on the market so there was very little for me to work with." Because the data for "Otezla wasn't any better and was much worse than all of the competitors, it was very difficult to find the value" to support the reimbursement application models. FE 15 provided the Otezla models for the reimbursement applications to Zhang, Celgene's Global Head of HEOR, Pricing and Market Access, who in turn presented them to Defendant Smith.

103. As recounted in the Class Action Complaint, based on his review of the Otezla Phase II and Phase III trial data, FE 16, a high-ranking member of HEOR and Pricing for the U.K., stated that Otezla was inferior to its biologic competitors in terms of response rate and efficacy. It was his understanding that Otezla had a response rate that was 50% of the rate of biologics. Otezla's main advantage was that it was a pill, but the response rates for patients taking Otezla were "nowhere near" a biologic like Humira.

104. FE 16 confirmed that, in the United Kingdom, Celgene's strategy was to discount Otezla to just below the price of its biologic competitors to stimulate sales and capture market share. But clinicians and patients were not swayed by the discount because the clinician would put the two drugs side by side, and the modest discount was not enough to make a difference with such an inferior efficacy. As FE 16 further explained, it was aggressive and foolish to assume that clinicians would use Otezla over biologics—clinicians just want to use the best product with the best data. As a result, FE 16 recounted that the Otezla sales and uptake forecasts compiled by Celgene for the United Kingdom and Ireland were overly aggressive. FE 16 added that his colleagues in other parts of Europe shared the same feeling that the Company's targeted sales figures were quite aggressive. FE 16 and his European counterparts at Celgene participated in discussions with independent advisory boards comprised of clinicians, local payers and various stakeholders. Those board members would consistently criticize Celgene, stating: "You're offering a biologic-like price without . . . biologic-like efficacy."

105. According to FE 16, once Otezla was introduced into the United Kingdom in late 2016, sales and uptake were "very slow and very low." FE 16 stated that they missed sales targets for five or six quarters and were continuing to struggle as late as the middle of 2018. The early sales targets were off by close to 50%. FE 16 confirmed that both Celgene's European and U.S. leadership knew of the missed targets. Indeed, there was "business review meeting after business review meeting" concerning the missed targets, including, at one point in late 2016 or early 2017, a meeting in London between Defendant Smith and Business Unit Director Rob Moore.

V. Defendants Curran and Smith Are Told About Otezla's Sales Issues by Q3 2016

106. Throughout 2015 and 2016, Defendants represented to the investing public, including Plaintiffs, that Celgene would meet its 2017 Otezla guidance of net product sales of $1.5 to $2 billion.

107. Notwithstanding these statements made to the investing public, as recounted in the Class Action Complaint, according to FE 17, a senior-level U.S. Market Access executive between early 2016 and late 2017, there was no Otezla revenue growth anywhere by 2016. FE 17 recalled that the lack of growth in Otezla sales and its fundamental causes were expressly communicated to the IIEC by no later than the third quarter of 2016. At this time, the IIEC was comprised of at least the following individuals: Defendant Smith; Defendant Curran; Tessarolo; Hunter Smith (Vice President, Finance); Tom Tomayko (Vice President, Commercial Development & Strategy, I&I); and Celgene's Head of Medical.

108. FE 17 and his team presented to the IIEC one to three times during each of the third and fourth quarters of 2016. Jim Kilgallon, Executive Director, U.S. Market Access, Pricing and Contracting, who worked with FE 17 and maintained much of the supporting Otezla payer and pricing statistics, presented with FE 17 at these meetings. During these presentations, which focused on payers and pricing, FE 17 and his team expressly warned the IIEC that the 2017 Otezla guidance could not be met. FE 17 explained that the detailed research he reviewed and presented regarding payers and pricing showed that the forecasted Otezla sales for 2017 were not attainable. According to FE 17, Tessarolo also warned the IIEC in weekly meetings by the third quarter of 2016 that the 2017 Otezla guidance could not be met.

109. The Class Action Complaint also alleges that in the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. FE 17 also specifically recalls that he and Kilgallon told Tessarolo directly that the guidance needed to be lowered. Tessarolo agreed and later confirmed to FE 17 that he, too, warned the IIEC that the guidance should be lowered, but the other members of the IIEC, which included Defendants Smith and Curran, insisted that the guidance would not be changed. Thus, FE 17 confirmed that by the

third and fourth quarters of 2016 the IIEC was acutely aware that Celgene was not going to hit the repeatedly reaffirmed 2017 Otezla sales guidance numbers. According to FE 17, "everyone knew that the actual stated forecast was not reasonable" and could not be met.

110. FE 17 further recounted that the Forecasting team (which included Doug Bressette, Senior Director, Global Business Planning and Analysis for I&I) was "told to change" the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth.

111. According to the Class Action Complaint, FE 18, a direct report to Swartz, Celgene's Vice President of U.S. Market Access, confirmed that Smith and other Celgene executives were aware that Celgene was not going to meet its 2017 Otezla sales guidance by no later than the fourth quarter of 2016. FE 18 explained that Swartz made recommendations to the Corporate Pricing and Market Access Committee ("CPMAC")—the committee charged with monitoring and approving pricing and market access decisions—that the Company needed to reduce the 2017 guidance numbers, but she was ignored. The CPMAC was chaired by Defendant Smith, and other members of Celgene's senior executive management would attend as well.

112. When FE 18 first saw the 2017 Otezla sales guidance, his reaction was "wow, there is no way in the world we were going to make [it] . . . it was crazy." FE 18 described the guidance as a "moon shot." FE 18 indicated that the aggressive Otezla guidance did not even account for the introduction of new competition to the psoriasis and psoriatic arthritis market—Defendants simply ignored this factor. FE 18 further explained that the guidance figures were based on the assumption that insurance reimbursement hurdles would be removed. To meet the Otezla sales numbers set by the CPMAC, Otezla would have had to completely transform the market space in less than twelve months—but this kind of transformation is unheard of, unless a company introduces a curative drug. Otezla just did not have the efficacy or novelty to bring about the

market change needed to meet the Company's sales guidance. FE 18 also confirmed that Otezla sales in the fourth quarter of 2016 were very flat and had been flat for quite some time before that.

113. Defendants ignored these warnings that Otezla's 2017 sales guidance could not be achieved. Indeed, according to the Class Action Complaint, FE 17 stated that Defendants refused to lower the guidance and instead pressured salespeople to hit the impossible numbers.

114. The Class Action Complaint alleges that according to FE 18, Swartz was fired in late 2017. FE 18 had reported to Swartz for a year and a half and never had any issues with her, stating that she was always very professional and was a great boss for whom to work. The consensus among FE 18 and his colleagues was that Swartz had been fired due to her consistent pushback regarding the unachievable Otezla sales guidance that Celgene repeatedly provided to the market. According to FE 18, Swartz was "scapegoated" and her termination was an attempt by Celgene to "pivot around her."

VI. In January 2017, Celgene Promises 57% Otezla Growth and up to $1.7 Billion in Sales, Despite Internal Knowledge That Those Goals Were Unachievable.

115. On January 9, 2017, Celgene filed a Form 8-K with the SEC attaching a press release that included the Company's 2017 outlook. The press release reported that the Company expected 2017 Otezla sales to range from "[a]pproximately $1.5B to $1.7B" with "57%" year-over-year growth from 2016.

116. Analysts reporting on Celgene's press release, including BTIG Equity Research, wrote that the "biggest driver" of the Company's overall 2017 guidance was Otezla, "which is expected to grow ~58% YoY." SunTrust Robinson Humphrey wrote that even the narrowed Otezla guidance range "calls for significant growth." In addition, several analysts noted that Celgene's reaffirmation of the $1.5 billion low-end of the guidance range was in line with the market's expectations. For example, RBC Capital Markets was focused on the low end of the

range, writing on January 9, 2017 that the $1.5 billion figure was "already expected." Evercore ISI wrote in a January 9, 2017 report that "CELG took the top end of Otezla guidance down from $2B to $1.7B, and the midpoint of Otezla guidance now tracks with consensus 2017 estimates of $1.54B." Similarly, J.P. Morgan stated in a January 9, 2017 report discussing Celgene's updated 2017 guidance that the consensus guidance for Otezla was $1.53 billion.

117. According to the Class Action Complaint, multiple former employees confirmed that Defendants' forecasted 57% year-over-year growth was both unrealistic and unachievable. FE 19, a senior executive in U.S. Field HEOR, recounted that based on what his Market Access group was seeing in their interactions with and analyses of large payers, there was no way that the projected 57% year-over-year Otezla sales growth for 2017 was attainable. According to FE 19, in late 2016, when Defendant Smith was assessing the 2017 Otezla market access and setting the targets, the market did not support anything close to 57% growth. FE 19 continued, "even if Market Access was able to obtain 100% coverage [from insurance companies], it was unrealistic to obtain the kind of growth in Otezla sales that Smith was forecasting for 2017."

118. As FE 19 explained, Otezla's competitors, including Humira and Remicade, were deeply entrenched in the market space, which made it increasingly difficult for the sales team to come anywhere close to Smith's projections. FE 19 stated that in light of physicians' reluctance to prescribe Otezla over well-established competitor drugs, reaching the sales projection was "not going to happen." FE 19 recalled having conversations with Swartz and Claudio Faria, Executive Director and Group Lead of U.S. HEOR, concerning the unrealistic sales projections given what Market Access was reporting to management. According to FE 19, there was no way Defendant Smith could have interpreted what his Market Access team was saying and translated that into 57% sales growth for Otezla in 2017.

119. The Class Action Complaint also includes allegations from FE 17, who detailed multiple impediments to Celgene meeting the Company's 2017 Otezla sales guidance, and achieving the publicly-stated 57% year-over-year growth. FE 17 attributed the overall lack of growth in Otezla sales observed throughout 2016 and into 2017 to three main factors: (i) managed care was "underwater" by April 2016; (ii) as early as April 2016, new Otezla prescriptions and patients were down; and (iii) Celgene allowed wholesalers to buy in above their demand in late 2016. With respect to managed care being "underwater," FE 17 explained that when Celgene enters into a new PBM contract that requires Celgene to issue rebates, the Company ends up paying rebates for all existing prescriptions—*i.e.*, the rebates apply both to new prescriptions and existing prescriptions. By virtue of the massive rebates due on the existing prescriptions, the PBM contracts are deemed "underwater" and undermine sales revenues. As early as April 2016, the rebates due on existing Otezla prescriptions covered by these "underwater" contracts were "significant" and amounted to millions of dollars. FE 17 stated that Celgene management should have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues. But no warning was given.

120. The Class Action Complaint also includes allegations from FE 17 that Celgene permitted wholesalers to purchase Otezla at reduced prices in excess of actual demand in late 2016, in advance of a planned 2017 price increase. This decision, which FE 17 stated was motivated by management's desire to make the fourth quarter 2016 Otezla numbers look great, had a negative impact on the revenues in the first quarter of 2017, and thus Celgene's ability to meet its 2017 Otezla sales guidance.

121. The Class Action Complaint also includes allegations that FE 7 confirmed that achieving a 57% increase in Otezla net product sales was "impossible" given Celgene's "pay to play" strategy, described above. FE 7, who identified multiple barriers to Otezla's ability to capture market share described above, added that "there isn't any way to grow [Otezla] revenue by 57%." FE 7 was very vocal to senior management (including Alles and Defendants Smith and Curran) and specifically told them that he did not think Otezla's growth would continue because of the step-edit hurdles and the saturation of competitor drugs in the market.

122. The Class Action Complaint recounts that FE 8 corroborates these allegations, with FE 8 stating that there was no way Celgene could meet the 57% year-over-year growth forecasted as part of the January 2017 Otezla guidance. FE 8 stated that Otezla sales continued to be flat into April 2017 and, as a result, he and his Regional Business Manager were "banging their heads against the wall."

123. FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that Celgene needed to downgrade its 2017 Otezla sales guidance.

124. As alleged in the Class Action Complaint, by as early as October 20, 2016, Curran and other Celgene executives received and discussed information about the methodology Celgene used to calculate the 2017 Otezla Budget and subsequent LEs and other internal forecasts. Based on discovery in the Class Action, the Class Action Complaint alleges that the "outputs" that formed the basis of those broader Celgene forecasts consisted of (1) Units, Gross Revenue, and Net Revenue; (2) Demand & Inventory; and (3) Otezla Market Shares (psoriasis and psoriatic arthritis), which also relied on assumptions relating to the size and growth of the overall psoriasis and psoriatic arthritis markets involving other competitors.

VII. Unbeknownst to Investors, Defendants Knew That 1Q 2017 Performance Did Not Support 2017 Public Guidance

125. With confirmation from internal Celgene documents received in discovery, the Class Action Complaint alleges that throughout the first quarter of 2017, Curran and other senior Celgene executives received, discussed, and shared internally presentations and other information showing that the performance of the Otezla business, as assessed through sales, inventory, demand, and market metrics, substantially underperformed the forecasted 2017 Otezla Budget, and that there was no reasonable basis to represent to investors that Celgene would meet its full-year 2017 Otezla public guidance.

126. With confirmation from internal Celgene documents received in discovery, the Class Action Complaint alleges that, throughout the first quarter of 2017, Curran and other senior Celgene executives received, discussed, and shared internally presentations and other information showing the large amount of Otezla inventory on hand that Celgene had with distributors at the beginning of the first quarter of 2017, which depressed Otezla sales demand. Curran and senior Celgene executives also received, discussed, and shared internal presentations and other information showing declining, or flat, Otezla sales metrics, which ultimately led to a significant downward variance between actual Otezla sales and net revenue and those forecasted in the 2017 Budget. Curran and other Celgene executives further received, discussed, and shared internal presentations and other data showing that there was an overall contraction in the psoriasis and psoriatic arthritis drug markets, which posed a risk to Otezla's shares of those markets and comprised material risks to Otezla's 2017 net sales and revenue.

127. On January 31, 2017, Mark Kreston, I&I's Head of Global Marketing, emailed Hunter Smith, I&I's Vice President of Finance, regarding a regular "Otezla Invoiced Shipments" report, for which Curran and other I&I executives were members of the distribution list. Kreston

wrote, "We are lagging big time – any feel for why? Strong December buy-in?" Hunter Smith responded that "the answer is that we are long past digestion of the December buy-in so the issue is demand."

128. On February 8, 2017, Celgene's Executive Director of Corporate Financial Planning and Analysis, Steven Rosen, emailed Celgene CFO Peter Kellogg with the subject "Revenue Update – US Otezla Q1 QTD." Rosen's email referenced "the discussion at last week's EBR [Executive Business Review] meeting regarding U.S. Otezla trends" and stated that "we wanted to give you a forewarning regarding the ongoing trend which continues to be soft." He characterized the sales trend as being "significantly below where we would expect," and that "a 73% increase on the average daily sales to date is needed to achieve the Budget." Rosen declared that it would thus "take a very significant uptick to meet the budget."

129. On February 14, 2017, Celgene's Senior Vice President of Finance Jurg Oehen sent an email to Celgene CEO Alles and CFO Kellogg entitled "Q1 trends and forecast considerations." The email, which said it was "a brief update on our thoughts on the Q1 trends and the related forecast," stated that "Otezla sales have been very soft so far." Oehen stated that "[t]o make the Q1 forecast, we would need to see a very significant revenue acceleration in the remainder of Q1 (US sales would need to increase by roughly 100% above the levels we have seen until now)." CFO Kellogg responded to Oehen (and included Alles) that it was "important to note that the Street is well ahead of this Budget/forecast for Otezla, so that will be the main issue for Q1, even if we get back to Budget." He remarked further that "we should plan our verbal commentary, and whether there should be some pre-emptive signaling during the Quarter to get the street better aligned." In a subsequent email, Kellogg wrote that "[w]e should start with [Defendant] Scott

[Smith], to get his sense of where he feels the business will land in the Quarter. Shipments this week didn't pick up."

130. On February 21, 2017, Curran received an email from Tessarolo that attached a slide presentation "[f]or review in our 9am meeting," which Curran requested to be printed. A slide in that presentation, entitled "Latest Thinking Summary," reduced the total number of forecasted Otezla unit sales for the first quarter of 2017 from 141,776 units (as set forth in the 2017 U.S. Budget) to 117,300 units (a greater than 17% reduction) – while retaining the budgeted forecasted units for the remaining three quarters. The slide reflected I&I's "latest thinking" that Otezla's total unit sales for 2017 would miss the 2017 U.S. Budget forecast by approximately 24,500 units. That same presentation further indicated that I&I's "latest thinking" was that full-year 2017 net revenue would be 1,279.6 million, a $29.6 million downward variance from the 2017 U.S. Budget.

131. On February 24, 2017, Oehen emailed Hunter Smith and asked him to provide "an updated forecast to Senior Management for discussion." Hunter Smith responded that "Terrie [Curran] has updated numbers and can talk to them," stating that the latest thinking for the Global I&I franchise was "$258 net (-$34 million vs. budget)." Oehen replied to Hunter Smith that "we need more regular automatic updates from I&I and one source of the truth." Oehen thereafter forwarded the email exchange to CFO Kellogg, stating that the "updated forecast seems very ambitious and I have serious doubts on whether we will get there."

132. According to facts pled in the Class Action Complaint based on internal Celgene documents received in discovery in the Class Action, in an IIEC meeting on March 7, 2017, Curran received and discussed I&I's "latest thinking" that Otezla's net revenues would significantly underperform the 2017 U.S. Budget. The presentation proposed that the March 2017 LE be

downgraded from the first quarter of 2017 U.S. Budget forecast of $255.7 million to $215.2 million, a reduction of $40.5 million against the U.S. Budget. That same presentation stated that Otezla's EMEA (Europe Middle East Asia) sales were lagging 18% behind the 2017 EMEA Budget for the first quarter of 2017.

133. On March 8, 2017, members of the I&I Finance team prepared a draft slide presentation that included another "Latest Estimate Summary." The Class Action Complaint alleges, based on a review of that presentation received in discovery, that the summary forecasted a further decrease in units for the first and second quarters of 2017 (down to 116,600 and 152,400, respectively), but increased the units forecasted for the fourth quarter of 2017 – raising the fourth quarter units forecast from 193,052 to 200,900 units. The next day, March 9, 2017, Finance team members prepared and emailed an updated slide deck to Curran, entitled "Q117 LE Review Slides-post Terrie_Huntermeeting.pptx." The "post Terrie_Huntermeeting" presentation also included an updated "Latest Estimate Summary." That updated version further increased the fourth quarter of 2017 forecasted units (from the presentation the day before) by an additional 8,000 units to 208,800 units – an increase of over 15,000 total units added onto the fourth quarter of 2017 forecast from the 2017 U.S. Budget.

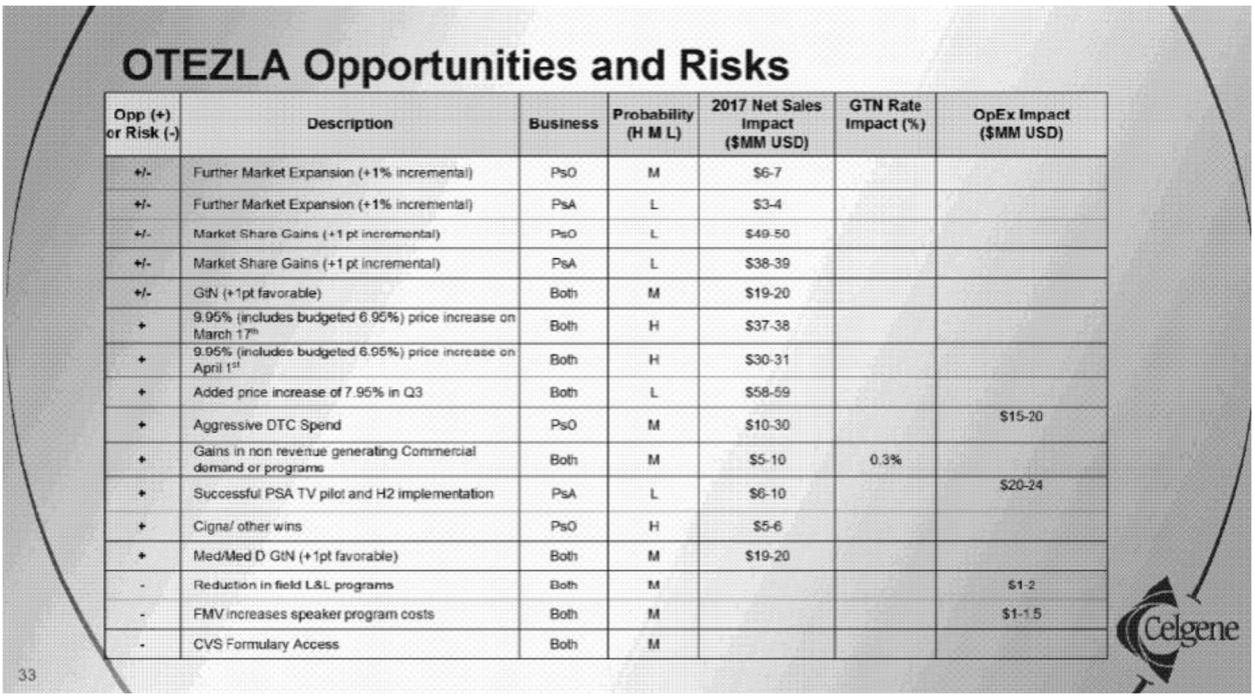
134. During a presentation to the IIEC on or about March 7, 2017, Celgene executives received and discussed a slide entitled "Market Growth Appears to be Cooling – PsA and PsO." ("PsA" refers to psoriatic arthritis and "PsO" to psoriasis.) Three days later, on March 10, 2017, Curran emailed Defendant Smith, stating: "Interesting. As [I] . . . look more closely, market growth does seem to be cooling in both segments." That same day, Curran received the "post Terrie_Hunter meeting" presentation, a subsequent version of which she forwarded to Celgene executives in connection with a meeting to discuss Otezla's actual and forecasted 2017

performance. A slide from that presentation, including the version that Curran forwarded to Defendant Smith, stated that "Market Growth in both PSO and PSA is cooling," "PsA Market Growth has slowed," and "[g]rowth [was] already decelerating in 2016."

135. On March 15, 2017, Curran emailed a slide presentation from a March 13, 2017 EBR meeting with Celgene executives entitled "Q117 LE Review Slides_TC_Deck march 13 v02.pptx." That presentation referenced a "Q1 shortfall of 25k units vs. Budget." The March 13 "TC-Deck" presentation also included a "Latest Estimate Summary," which the Class Action Complaint alleges assumed a 9.95% price increase for Otezla as of April 1, 2017 – an increase that was 3% higher than the price built into Celgene's 2017 Budget and never adopted by Celgene.

136. As Douglas Bressette, Senior Director, Global Business Planning and Analysis for I&I, recognized in an email to a colleague in March 2017, "Without 9.95% price, we were never going to hit the [$]1,309 [billion]"—*i.e.*, Celgene's forecast for 2017 U.S. Otezla sales that was built into the 2017 Budget.

137. The "TC-Deck" also included an "OTEZLA Opportunities and Risks" slide, which quantified the "2017 Net Sales Impact" based on a variety of opportunities and risks, including market expansion (or contraction), market share gains (or losses), and price:



OTEZLA Opportunities and Risks

Opp (+) or Risk (-)	Description	Business	Probability (H M L)	2017 Net Sales Impact ($MM USD)	GTN Rate Impact (%)	OpEx Impact ($MM USD)
+/-	Further Market Expansion (+1% incremental)	PsO	M	$6-7		
+/-	Further Market Expansion (+1% incremental)	PsA	L	$3-4		
+/-	Market Share Gains (+1 pt incremental)	PsO	L	$49-50		
+/-	Market Share Gains (+1 pt incremental)	PsA	L	$38-39		
+/-	GtN (+1pt favorable)	Both	M	$19-20		
+	9.95% (includes budgeted 6.95%) price increase on March 17th	Both	H	$37-38		
+	9.95% (includes budgeted 6.95%) price increase on April 1st	Both	H	$30-31		
+	Added price increase of 7.95% in Q3	Both	L	$58-59		
+	Aggressive DTC Spend	PsO	M	$10-30		$15-20
+	Gains in non revenue generating Commercial demand or programs	Both	M	$5-10	0.3%	
+	Successful PSA TV pilot and H2 implementation	PsA	L	$6-10		$20-24
+	Cigna/ other wins	PsO	H	$5-6		
+	Med/Med D GtN (+1pt favorable)	Both	M	$19-20		
-	Reduction in field L&L programs	Both	M			$1-2
-	FMV increases speaker program costs	Both	M			$1-1.5
-	CVS Formulary Access	Both	M			

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Celgene

138. As shown above, the presentation quantified the risk of an overall market contraction at approximately $6-7 million per each percentage point contraction in the psoriasis market and $3-4 million per each percentage point contraction in the psoriatic arthritis market. The presentation further quantified the risk of decreased Otezla market share at approximately $49-50 million per each percentage point reduction in Otezla's market share of the psoriasis market and at approximately $38-39 million per each percentage point reduction in Otezla's market share of the psoriatic arthritis market:

139. On March 23, 2017, CEO Alles' Chief of Staff emailed Defendants Smith and Curran with the subject line "Monday's EBR Meeting," writing "At Monday's EBR meeting, in addition to an LE update, we would like to discuss Otezla sales/market trends, etc." Curran forwarded the email to Hunter Smith and other I&I executives. Hunter Smith replied, "Based on conversations w[ith] [Defendant] Scott [Smith] yesterday, I think it's key to understand both volume and price sensitivity of the full year LE."

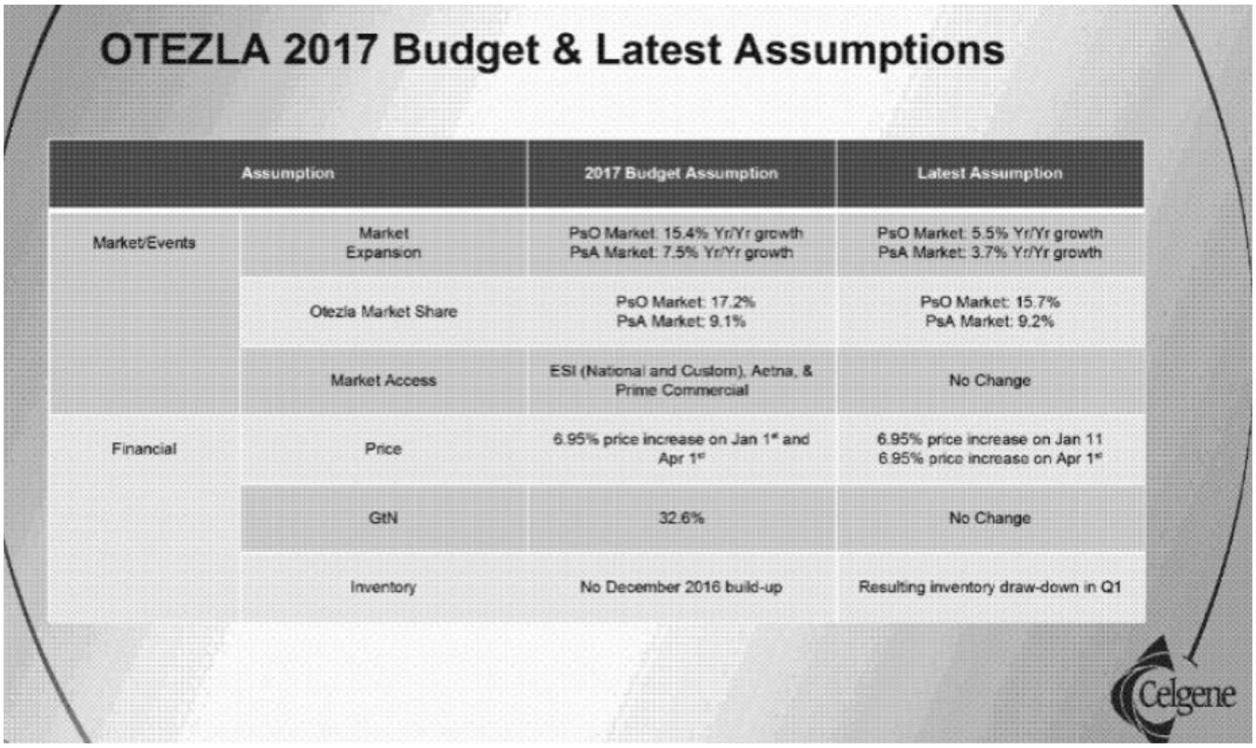
140. The Class Action Complaint alleges that later on March 23, 2017, I&I Finance executives exchanged emails regarding the unit sales run rate from the first quarter 2017 and whether that run rate could support meeting the second quarter 2017 budget. According to the Class Action Complaint, those emails showed that I&I Finance executives first determined the amount of weekly sales needed to achieve the March 2017 LE, and then calculated the necessary growth rate to hit that target. On the morning of March 23, 2017, Bressette, Senior Director, Global Business Planning and Analysis for I&I, emailed other I&I Finance executives stating that the "Q2 LE is $308M. How much unit growth is necessary for each scenario to get to the $308M." Later that afternoon, Bressette emailed Hunter Smith with the subject "Q1 Run rate build to Q2." Bressette explained that he had "modeled the units needed each week to hit forecast. I then modeled revenues based on different price assumpts. Last column to the right is the number of additional unit[s] needed to hit Q2 revenue LE at each price." The Class Action Complaint alleges that the attached spreadsheet shows that Bressette had not relied upon any of the forecast methodologies underlying the 2017 Budget to forecast unit sales; rather, he simply created a basic mathematical formula to calculate the necessary week/week growth rate to satisfy the pre-established March 2017 LE units forecast.

141. On March 27, 2017, Curran received an email with an attachment entitled "EBR SLIDES for Terrie March 27, 2017," referencing an EBR meeting that same day with Celgene executives. The Class Action Complaint alleges that the presentation set the March 2017 LE at $201 million for U.S. net revenue, a reduction of approximately $55 million from the first quarter of 2017 Budget; and at $43 million for Rest of World (ROW) net revenue, a reduction of approximately $7 million from the first quarter of 2017 Budget – for a total reduction of $62

million from the 2017 Global Otezla Budget, or 25%. The presentation acknowledged that "[i]nventory adjustment" was one of the leading factors "driving Q1 weakness."

142. The March 27 EBR presentation also referenced the overall psoriasis and psoriatic arthritis market, stating that overall psoriasis and psoriatic arthritis market prescription "Volumes Show Consistent Weakness in Q1."

143. One slide provided to Curran prior to that presentation set forth I&I's latest assumptions regarding the overall psoriasis and psoriatic arthritis markets, which showed a significant downward variance from the original 2017 Budget:



144. Thus, the slide assumed that, rather than the 15.4% year-over-year growth rate for the psoriasis market that Celgene had incorporated into the 2017 Budget, the psoriasis market would experience the far lower growth rate of only 5.5% year-over-year. The slide further assumed that the psoriatic arthritis market would decline from the 7.5% year-over-year growth rate built into the 2017 Budget down to only 3.7% year-over-year growth. And it assumed that Otezla's

psoriasis market share would decrease by approximately 1.5% from what was assumed in the 2017 Budget. Altogether, as alleged in the Class Action Complaint, the 9.9% decrease in the growth rate for the psoriasis market, the 3.8% decrease in the growth rate for the psoriatic arthritis market, and the 1.5% decline in Otezla's expected market share of the psoriasis market reflected an approximately $140 million risk to the 2017 Budget and Celgene's public guidance, based on I&I's "Opportunities and Risk" assessment.

145. Curran recognized that Celgene's Board of Directors might react negatively to Otezla's market share being flat, at best. In response to a draft slide deck that Curran received for an upcoming Board meeting, on April 14, 2017, Curran wrote, "Just met re Q1 and Bod messaging . . . Feedback re BOD deck—don't like market share as it looks flat."

VIII. Problems Persist Into Q2 2017, But Celgene's Public Guidance Remains Unchanged

146. Otezla sales for April 2017 did not increase to the level needed to make up for the substantial first quarter 2017 shortfall. On April 10, 2017, Oehen forwarded the Daily Sales Report to Rosen, commenting, "Otezla is on track to … again miss the forecast." Nor did sales improve appreciably the next week, either. On April 18, 2017, Rosen forwarded the Daily Sales Report to Oehen, writing, "Another challenging Monday for Otezla." He stated that "we are falling further behind every Monday." Oehen replied, "Indeed very disappointing sales and hard to belie[ve] that they will get close to their Q2 forecast."

147. During a presentation to Celgene executives on April 24, 2017, Curran confirmed that Otezla's market share was not growing in either the psoriasis or psoriatic arthritis markets, including a slide that read "Q1 Otezla market shares relatively flat in both PsO and PsA."

148. According to the Class Action Complaint, on April 26, 2017, Curran and other Celgene executives received a presentation with Otezla U.S. Performance data showing that Otezla's actual net revenue was only 83% of the 2017 U.S. Budget for the year-to-date. The

presentation further confirmed that April sales were at the level forecast originally in the 2017 Budget, and that they thus had not made up any ground from the 27,000 sales unit shortfall in the first quarter of 2017. In addition, Otezla's new prescription ("NRx") metric was negative for the 4-week/4-week period and was -2.02% below NRx growth year/year. The presentation also indicated that the overall market had contracted, with declines of approximately 4% in the psoriasis market over the 4-week market volume metric and approximately 3% in the psoriatic arthritis market over the 4-week market volume metric.

149. Celgene executives also knew that given the rebates and discounts that the Company was providing on Otezla, that meeting the 2017 Otezla budget was dependent on significantly increasing market share for the drug. For example, on September 16, 2016, Tessarolo wrote to Defendants Smith and Curran, and Hunter Smith, that achieving even an Otezla sales "neutral" scenario in 2017 "will require us to drive significantly more demand in these plans in 2017," and that "[f]ailing to deliver an inflection in market share would risk performing to our currently submitted 2017 Budget." But as alleged in the Class Action Complaint based on discovery received in the Class Action, internal Celgene data in the first quarter of 2017 showed that Otezla's market share through three critical PBMs—Aetna, ExpressScripts, and Prime—were lower than forecasted.

IX. Celgene Reports First Quarter 2017 Results and Reaffirms Aggressive Guidance

150. During the April 27, 2017 conference call about Celgene's first quarter results, Kellogg stated that "[s]trong growth was achieved across the portfolio, with key contributions by" several drugs, including Otezla. He then "reminde[d]" participants that "the sequential performance from Q4 to Q1 is always impacted by several items," and that Otezla "is impacted by managed care dynamics that drive lower total marketplace prescriptions for psoriasis therapies in Q1."

151. Kellogg then discussed "a new dynamic for" Otezla in the first quarter, "a higher gross to net adjustment related to new contracts with several large payers that were implemented in January. These new contracts approximately doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy which has already improved OTEZLA's market share in these accounts. . . . In total and not surprisingly, the market dynamics that I just described across the portfolio resulted in a 1% sequential decline in net product sales from Q4."

152. Defendant Smith reported that global Otezla "net sales for Q1 2017 were $242 million, representing a 24% year on year increase. This revenue growth is being driven by continued gains of market share and geographic expansion." Although Smith stated that "uptake is accelerating internationally," he acknowledged that in the United States:

> the challenging dynamics we faced in Q1 were mainly driven by short-term headwinds. Beyond the normal Q1 market declines we anticipated, this year's contraction was deeper and more protracted. Additionally, we saw significantly higher GTN adjustments in Q1 due to contracting to remove biologic step-edits in several major U.S. health plans and a modest decline in inventory levels. We expect the increased GTN to be more than offset by future growth in these large plans.

153. Defendant Smith stated that Celgene saw "consistent growth" in Otezla "share in the large psoriasis market" and that the drug was "closing the share gap on" Stelara "for second position in the category," as well as "continu[ing] to expand the market and . . . lead[ing] all therapies in new-to-brand share for both psoriasis" and psoriatic arthritis.

154. During the question-and-answer portion of the conference call an analyst from UBS asked the below question about why Celgene was confident that Otezla sales would recover quickly:

> On OTEZLA, it definitely sounds like you're positioning the performance, the seasonal and sort of temporary and I guess very

> much in line with what we heard from Amgen last night in the broader segment. Can you just walk through what gives you confidence growth will bounce back or could we see continued pressure in the near term?

155. Defendant Curran responded to this question, reiterating Celgene's 2017 guidance for Otezla, among other positive statements:

> Thank you, Carter. Yeah, I think you're spot on. I think there was really three key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased GTN [gross to net] as a result of the contracting, but importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw minimal drawdown of the inventory.
>
> Importantly, if we look at the underlying dynamics to the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients and these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter one and into quarter two, we do see the net sales rebounding and on track to deliver the 2017 guidance.

X. Removal Of Insurance Step-Edits and New PBM Contracts Would Not Save Otezla Sales

156. Although both Defendants Smith and Curran referenced the removal of step-edits by insurance companies as a long-term positive development for Otezla's sales growth, the removal of those step-edits did not offset Otezla's other issues and there was no reasonable basis to conclude that the lack of those step-edits would result in significantly increased sales.

157. As alleged in the Class Action Complaint, according to FE 12, after Celgene spent a lot of money to have insurance companies remove step-edits and other requirements that stood in the way of coverage for Otezla prescriptions, there was a push from corporate and District Managers to increase sales volumes. But, as discussed above, there were numerous other issues that continued as drags on Otezla sales. As FE 9 confirms, even with step-edits removed, the sales

issues would not be cured, because, among other things, doctors had been prescribing competitor drugs for years and it was easier for them simply to continuing doing so.

158. According to the Class Action Complaint, during meetings in November or December of 2016 with Defendant Curran, Tessarolo, Swartz, Grausso, Willcox, and Ronald Owen, National Sales Director, FE 7 continued to warn these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges.

159. FE 7 indicated that while Celgene did get some step-edits removed for Otezla in 2017, Celgene's leadership had previously made decisions that hampered Otezla's market access and destroyed its "best price" beginning as early as the 2014 launch, as alleged above. In addition, not all payers agreed to remove step-edits, including United, Aetna, Cigna and Blue Cross Blue Shield. Furthermore, FE 7 stated that even if 10 million individuals obtained access to Otezla through the removal of step-edits, not all of them would actually buy Otezla. In short, the removal of the step-edits could close the gap between actual Otezla sales and Celgene's knowingly unreasonable 2017 guidance.

160. The Class Action Complaint alleges that, unbeknownst to investors, Defendants' April 27, 2017 representation that the newly-entered PBM contracts would help drive the Company's 2017 Otezla sales was undermined by the fact that many of the PBM contracts took several months to generate revenues and, as a result, the Company reduced the revenue expectations associated with these contracts.

161. Specifically, the Class Action Complaint alleges that FE 18 stated that several of the new PBM contracts Celgene entered into in 2017 covered patients who were receiving their Otezla prescriptions for free or at a reduced cost through various forms of patient assistance and other initiatives, such that Celgene was earning only minimal revenues related to these patients'

prescriptions. Even after the new PBM contracts became effective, these patients continued to receive their Otezla prescriptions at little-to-no cost until their prior entitlements expired, at which point they were brought under the new reimbursement scheme. FE 18 explained that it was not until this process was complete—which could take one or two years—that Celgene started to earn revenues on these prescriptions. Thus, even if new PBM contracts went into effect in 2017, Celgene did not see increased revenues from prescriptions for many covered patients until months later.

162. As alleged in the Class Action Complaint, FE 18 said that his Market Access team worked closely with the pricing team to assess how the new PBM contracts were performing throughout 2017. FE 18 stated that it was clear from the beginning of 2017, based on his team's monthly modeling, that the PBM contracts were not meeting revenue expectations. FE 18 communicated the fact that the contracts were underperforming to his boss, Swartz, and he understood that she reported this information to the CPMAC. According to FE 18, Celgene did not lower expectations for the PBM contracts even when presented with data showing that the contracts were underperforming; by contrast, when his team presented data showing that some contracts were outperforming, Celgene quickly raised the revenue expectations for those contracts.

163. Celgene eventually internally lowered the expectations on many of these PBM contracts. FE 18 recalled seeing a bar graph that depicted the original expectations, the actual numbers, and a revised, lowered expectation. The original expectation was "through the roof." Although the revised expectations were closer to the current performance, this was after they had been significantly lowered—by amounts that "took [him] aback." Rather than communicate this to public investors, including Plaintiffs, Defendants left the market with the false impression that the new PBM contracts would help increase Otezla's 2017 sales.

XI. Otezla Performance Worsens in Q2 2017

164. According to the Class Action Complaint, a May 22, 2017 presentation (including underlying data that was attached to, and incorporated into, the slide deck itself) provided to Curran and other Celgene executives in advance of an EBR meeting showed that Otezla's psoriasis market share had declined from year-end 2016 through the end of the first quarter and into April 2017. Similarly, a slide prepared as of June 12, 2017, in advance of a June 2017 meeting with Celgene executives, including Curran, stated that "Market TRx volumes in April and May (MTD) indicate PsO/PsA market is flat."

165. Indeed, Otezla's market share for both psoriasis and psoriatic arthritis decreased in the second quarter of 2017 under Celgene's own internal metrics. According to the Class Action Complaint, Otezla performance slides, received by Defendant Curran and other Celgene executives on April 20, 2017, and July 19, 2017, respectively, showed that the psoriasis 4-week market share metric (which included seven drugs, including Otezla) fell from 18.1% to 17.1% between March 31, 2017 and June 30, 2017. Similarly, those same performance slides, also received by Curran and other executives on April 20, 2017, and July 19, 2017, respectively, showed that the psoriatic arthritis 4-week market share metric (which included seven drugs, including Otezla) dropped from 7.8% to 6.9% between March 31, 2017 and June 30, 2017.

166. According to the Class Action Complaint, other key Otezla performance indicators declined in the second quarter of 2017. As Celgene's Executive Vice President of National Sales said in an email to other sales professionals on June 27, 2017: "We just didn't get it done against goal the first half – scripts and revenue." The same Executive Vice President told sales professionals a month late, on July 26, 2017, that Otezla prescriptions had to "dramatically increase" given the "flat lined" performance to date.

167. As in the first quarter, Otezla's net revenues also underperformed Celgene's 2017 Budget in the second quarter (by $7 million). U.S. Otezla sales also had a negative variance of over 6,000 total unit sales from the 2017 Budget in the second quarter. In addition, as depicted in a slide contained within a July 19, 2017 presentation received by Defendant Curran and other Celgene executives, Otezla's rate of new patient growth decreased throughout the second quarter of 2017. Otezla's market share of New-to-Brand patients, as also expressed in presentations and internal Company data throughout the quarter, as well as in a presentation received by Curran and other Celgene executives on June 26, 2017, also remained relatively flat over the quarter. A presentation dated July 31, 2017, entitled "Otezla LE Update Q3-Q4 2017," further showed a decrease in the "New Patients by Month End" through June 30, 2017.

168. A presentation received by Defendant Currant and other I&I executives on May 9, 2017 referenced an Awareness, Trial, and Usage ("ATU") study from a third-party that measured patient and doctor satisfaction with Otezla. The study concluded that "Fewer than half of [dermatologists] are confident that patients will be satisfied with Otezla, putting it well below all other therapies but MTX [methotrexate]." Otezla ranked lowest in the markets for psoriasis and psoriatic arthritis.

169. In addition, as alleged in the Class Action Complaint, as stated in internal reports and communications that Curran and other senior Celgene executives received, discussed, and circulated, all three of the critical PBMs—Aetna, ESI, and Prime—underperformed their forecasted amount both in terms of total prescription volume and Otezla's within-plan market share of an eight-drug market basket.

170. Making matters worse, Otezla sales were being hurt by two new competing drugs, Cosentyx and Taltz. In its 2017 Budget, Celgene assumed that the launch of Taltz, an IL17

inhibitor, would have "no impact to Otezla" and that Taltz's "share gains" would come "mostly from biologics," rather than from Otezla (a non-biologic). But a May 9, 2017 presentation, received by Defendant Curran, stated, "After the launch of IL17s, Otezla's new patients growth is down in Q1 2017 compared to Q1 2016." An accompanying slide depicted Otezla's "New to Product TRx" as having decreased by 2,099 total prescriptions, or 12%, over the period of December 30, 2016 through April 7, 2017. In contrast, the two new IL17 inhibitors, Cosentyx and Taltz, grew by 97% and 35%, respectively, over the same period.

171. According to the Class Action Complaint, on July 19, 2017, Defendant Curran received a slide presentation showing that Otezla experienced a net revenue decrease of 10.6% over the preceding 6-week-over-6-week period. The full-year run rate for U.S. Otezla net sales was estimated at $1.078 billion, which was approximately $300 million less than the 2017 Budget. The slide deck showed that Otezla sales were tracking at approximately 84% to the June forecast latest estimate, and approximately 82% to the 2017 Budget—a figure that was virtually identical to the April 26, 2017 presentation from three months earlier.

172. Celgene even resorted to shifting sales into the second quarter. According to the Class Action Complaint, in 2016, Celgene accounted for pre-July 4 sales in the third quarter, but in 2017, the Company recognized the pre-July 4 Otezla sales in the second quarter. On July 19, 2017, Defendant Curran and other Celgene executives received slide presentations, which included sales trends with a disclaimer stating that "[t]he peaks and valleys in recent weeks represent fluctuations around holidays," including two holidays in the second quarter of 2017: Memorial Day and July 4th. The fluctuation in sales around July 4th and the week thereafter was so pronounced that the two weeks (one in the second quarter of 2017 and one in the third quarter of

2017) were averaged together for purposes of quantifying week-over-week growth—which still remained negative over a 6-week-over-6-week period at the end of July 2017.

173. The Class Action Complaint also alleges that Defendant Curran received weekly wholesaler inventory reports, which showed that Celgene exited June 2017 with suppliers holding an abnormally high Otezla inventory, measured by the "days on hand" metric (representing the number of days' worth of Otezla that the wholesalers held at a given point in time).

174. The Class Action Complaint also recounts that on July 24, 2017, Defendant Curran's assistant emailed a copy of "Terrie's slides" in connection with Celgene's upcoming earnings call on July 27, 2017, which "reflect[ed] edits from today's prep session." A graphic in Curran's presentation depicted Otezla's overall psoriasis market share on a month-to-month basis in the United States. Although that graphic did not quantify Otezla market share by specific percentages, the underlying data for the graphic (which was attached to, and incorporated into, the slide deck itself) demonstrated that Otezla's overall market share for a six-drug market basket decreased over the second quarter of 2017, from 22.5% as of March 31, 2017, to 21.7% on June 30, 2017.

175. On July 25, 2017, Curran wrote in an email that Otezla's market share was "flat" over the second quarter. In response, Bressette confirmed that Otezla's market share was "relatively flat." In a separate email to Celgene executives later that same day, Curran again wrote that "Overall Otezla's demand growth v. Q1 on relatively flat market share generally tracked the systemic/biologic market basket growth over the same period."

176. On July 26, 2017, Defendant Curran received feedback and suggested edits on a draft script that she had prepared in connection with her remarks and accompanying presentation at Celgene's July 27, 2017 earnings conference call for the second quarter of 2017. As alleged in

the Class Action Complaint, one of the edits, from CEO Alles's Chief of Staff, changed the meaning of Curran's presentation in a way that was directly contrary to what Curran knew to be the truth. Specifically, Alles's Chief of Staff suggested, contrary to internal Otezla data and Curran's own characterization of second quarter market share as "flat," that Curran should instead describe Otezla's performance in the second quarter of 2017 in the following terms: "Key OTEZLA performance indicators continue to strengthen and market share and prescriber adoption increased significantly in both the U.S. and internationally." Despite being aware of a multitude of facts and data that rendered this statement false and misleading, Defendant Curran accepted this edit.

177. According to the Class Action Complaint, the July 27, 2017 Otezla Daily Sales Report, with data through July 26, 2017, showed that Otezla sales were lagging significantly in July 2017, far behind the June 2017 forecast LE for the third quarter of 2017 and the full year. Although 86% of the selling days in July had elapsed to that date, Otezla sales had achieved only 53% of the June forecast LE for July 2017. Through 29% of the Otezla selling days for the third quarter of 2017, Otezla sales achieved only 18% of the June forecast LE for the third quarter. And with 57% of selling dates having elapsed in the year to date, Otezla sales achieved only at 44% of the June LE for full-year 2017.

XII. Defendants Finally Cut Otezla Guidance at the End of Q3 and Celgene Stock Plummets

178. Otezla's financial performance did not improve in the remainder of the third quarter of 2017. A September 8, 2017 presentation forwarded from I&I executives to Celgene's Finance Department and entitled "2017-2018 Executive Business Review.pptx," listed the "Latest Assumptive Scenario" for U.S. Otezla sales at a full-year "Run Rate" of $1.094 billion, which was well below the $1.309 billion forecast for U.S. net sales built into the 2017 Budget. The September

"Current Forecast" (at $1.12 billion) and "Upside" (at $1.145 billion) also trailed the June latest forecast and 2017 Budget significantly.

179. In a September 11, 2017 email to Celgene's Finance Department, Defendant Curran stated that Otezla's "[o]verall national market share [was] running flat vs increase forecasted in 2017." As alleged in the Class Action Complaint, Curran noted multiple factors contributing to the flat growth in 2017, including that new entrants had entered the market, which the 2017 Budget had not adequately accounted for, "[m]arket growth [is] slowing more than expected," and the managed care plans on which Defendants relied to drive uptake—and which Celgene had entered into substantially more expensive contracts in late 2016 in order to increase market access—were "having lower & slower uptake than forecasted."

180. Finally, at the end of the third quarter, Celgene could dissemble to public investors, including Plaintiffs, no more. On October 26, 2017, due to poor Otezla sales, Celgene announced that the Company was decreasing its 2017 Otezla guidance by more than $250 million, from a range of $1.5-to-$1.7 billion to $1.25 billion. The Company also lowered its I&I guidance from over $4 billion to a range of $2.6-to-$2.8 billion.

181. During Celgene's October 26, 2017 conference call about its third quarter results, Alles claimed that Celgene's "2017 forecast assumptions did not adequately anticipate the deep and persistent slowing growth of the psoriatic arthritis and psoriasis markets, especially during the entire third quarter. When combined with the discounts tied to the execution of our ongoing managed-care contracting strategy, we missed our third quarter OTEZLA sales target." Kellogg similarly attributed the reduction in the Otezla guidance to the "market-wide challenges in the U.S. dermatology market," and Defendant Curran cited the "market deceleration" and characterized the Otezla market as "increasingly dynamic and competitive."

182. On the October 26, 2017 conference call, Defendant Curran further explained that Otezla's global net sales were only $308 million for the quarter—which was approximately $100 million below the 2017 Budget. Curran also acknowledged that Celgene missed its optimistic budget assumptions for Otezla, stating that Otezla instead experienced "lower-than-expected revenue due to market deceleration, increase in gross-to-net discounts to drive biologic step free access and inventory fluctuation." In addition, Curran stated that Otezla's market share "has been somewhat impacted in patients previously exposed to biologics." Curran also stated that "declined script volume became more prominent" in the third quarter of 2017. According to Curran, declining script volume, combined with "the market's softening, increased competition, as well as the impact from GTN" led to disappointing third quarter of 2017 results.

183. But as recounted in the Class Action Complaint, FE 18 rejected Defendants' claims that the Otezla miss was due to a slowing of the psoriasis and psoriatic arthritis markets, particularly during the third quarter of 2017, as well as increasing competition, calling this purported explanation "bullshit." FE 18 explained that there was no way that Celgene's leadership was unaware of the fact that there would be more products entering the market in 2017. In addition, FE 18 confirmed that the market did not change rapidly in the third quarter of 2017. As he explained: "We saw what was happening way before then. We had monthly meetings with the contract and pricing teams . . . very early on in 2017." FE 18 stated that there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people." Thus, according to FE 18, there was no way that Celgene's leadership was unaware of the looming guidance miss long before the third quarter of 2017.

184. Following Celgene's guidance reduction, J.P. Morgan wrote in an October 26, 2017 report:

> A week after a high-profile (albeit also high-risk) Phase 3 asset failed [GED-0301], the company reported a big miss for Otezla and a sizable cut to overall 2020 guidance. This is clearly not a recipe for success for an over-owned stock in a skittish market. The question now is what happens from here?

185. Raymond James put it bluntly: "today's update substantially alters our outlook and confidence in the company's ability to execute":

> We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a "show me" story.

186. On the news of the guidance reduction, the price of Celgene common stock cratered $19.57 per share, or more than 16%, from a closing price of $119.56 per share on October 25, 2017, to a closing price of $99.99 per share on October 26, 2017.

XIII. Celgene Acquires Ozanimod, Its Other Promised Revlimid Replacement

187. In addition to Otezla, Celgene also told the investing public, including Plaintiffs, that it would replace its Revlimid revenue stream with revenue from Ozanimod, which was initially developed to treat relapsing multiple sclerosis and ulcerative colitis.

188. On July 14, 2015, Celgene agreed to purchase another drug company, Receptos, for $7.2 billion. Through this acquisition, Celgene added Ozanimod to its drug portfolio. Celgene described Ozanimod as having demonstrated "several areas of potential advantage over existing oral therapies" for relapsing multiple sclerosis and ulcerative colitis. The Company projected annual Ozanimod sales of up to $6 billion. One analyst described Ozanimod as the "crown jewel"

in the Receptos acquisition. Indeed, Celgene increased its I&I 2020 revenue guidance from $3 billion to more than $4 billion after the acquisition.

189. After the acquisition, Celgene transferred its own personnel to Receptos' San Diego headquarters. As alleged in the Class Action Complaint, FE 20, a former senior executive in Clinical Development at Receptos, stated that "[t]hey [Celgene] were in charge. Receptos was not." FE 20 stated that decisions were made by Celgene from its New Jersey headquarters or by Celgene personnel in San Diego. FE 21 said that after the acquisition, Receptos' leadership was not allowed to make any decisions that could impact Celgene's stock price, and there were constant discussions between senior Receptos personnel and their counterparts and superiors at Celgene.

190. As the Class Action Complaint recounts, according to FE 20, Defendant Martin came from Celgene to Receptos to oversee the Ozanimod NDA filing. Martin formerly served as Vice President, Head of Project Leadership, for I&I. FE 2, who worked in Clinical Research & Development in I&I, described Martin as a "control freak" and Smith's right hand man, and confirmed that Martin was sent to San Diego as Managing Director for Receptos in late 2015 or early 2016. FE 2 recounted that Martin operated as the *de facto* chief executive at Receptos. FE 5, a former Director at Receptos, likewise described Martin as the CEO of Receptos after the acquisition, adding that Martin was in charge of the entire Receptos organization and reported directly to Smith.

191. FE 5 explained that once he was in power, Martin pushed out Receptos' previous upper management and replaced them with his friends from Celgene's New Jersey headquarters. Martin's best friend, Saillot, was brought in to serve as Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos. FE 5 also recounted that Gary Cline, Head of Strategic Research and Innovation at Celgene, was another individual sent by Smith to

San Diego to keep tabs on Ozanimod for Smith. FE 22, a Project Manager on the Ozanimod team, corroborated that Martin reported directly to Smith and further confirmed that Saillot was Martin's second in command.

XIV. Celgene Touts Ozanimod's Advantages Over Gilenya

192. Celgene knew that if Ozanimod received FDA approval, it would compete mainly against Gilenya, which treated relapsing multiple sclerosis and was made by Novartis. Thus, Celgene undertook to promote the purported advantages of Ozanimod over Gilenya and to rush Ozanimod through the FDA approval process.

193. Gilenya and Ozanimod work similarly. But Celgene claimed that Ozanimod had a much shorter half-life of 19 hours versus seven days for Gilenya. In practical terms, this meant that Ozanimod left the body much quicker than Gilenya. A short half-life meant that Ozanimod could be combined with other treatments or allow for a fast switch to another therapy, if needed. Thus, on September 9, 2015, during the Robert W. Baird & Co. Healthcare Conference, Defendant Smith pointed to the "different half-life . . . that you see with the S1P1 with Ozanimod, that you don't see with Gilenya," noting that this "could potentially be some reason to differentiate."

194. In October 2015, the U.S. Patent and Trademark Office invalidated a formulation patent on Gilenya. This ruling would have permitted generic Gilenya competitors to enter the market by the end of 2019. This also would also be bad for Celgene, as Ozanimod would have to quickly compete with generic Gilenya. As a result, Celgene was highly incentivized to file its Ozanimod NDA and seek FDA approval, in order to establish market share before the end of 2019, when generic Gilenya competitors would flood the market.

195. Celgene did not disclose that it believed there would be any obstacles to gaining FDA approval of Ozanimod. In announcing the Receptos transaction, Celgene explained that

Ozanimod "Phase III trials in UC and RMS underway; data expected beginning in H1:17 with first approvals in 2018."

XV. Drug Metabolites and Relevant FDA Guidance

196. After a drug is ingested, the body may break that drug down into a different substance, known as a metabolite. An active metabolite is one that continues to produce effects in the body after it is formed. Active metabolites thus can alter the safety and therapeutic effects of a drug. For example, the toxicity profile of the metabolite may differ from the parent drug, or the metabolite may remain in the body for a longer period of time than the parent drug. For this reason, federal regulations require that a new drug application include a "[h]uman pharmacokinetics and bioavailability section," including "[a] summarizing discussion and analysis of the pharmacokinetics and metabolism of the active ingredients and the bioavailability or bioequivalence, or both, of the drug product." 21 C.F.R. § 314.50.

197. Since 2008, the FDA has issued guidance for the drug industry on the safety testing of drug metabolites. Under the heading "General Concepts in Metabolite Safety Testing," the 2016 FDA guidance states: "We encourage the identification of any differences in drug metabolism between animals used in nonclinical safety assessments and humans as early as possible during the drug development process. The discovery of disproportionate drug metabolites late in drug development can potentially cause development and marketing delays." The guidance also states that "[m]etabolite concentrations cannot be inferred by measurement of parent drug concentrations" and that "[t]he metabolic profile of the drug should be identified during the drug development process." The guidance "strongly recommend[s] [that] in vivo metabolic evaluation in humans be conducted as early as feasible." Finally, under the heading "Timing of Safety Assessments," the guidance states that "[e]arly identification of disproportionate drug metabolites can provide clear justification for nonclinical testing in animals, assist in interpreting and planning

clinical studies, and prevent delays in drug development. If toxicity studies of a drug metabolite are warranted, studies should be completed and study reports provided to the FDA before beginning large-scale clinical trials."

198. A 2017 FDA presentation, "An FDA Perspective: Safety Testing of Drug Metabolites in Drug development" makes the same points as the 2016 guidance:

- When safety testing is needed?
  - Early (as feasible).
  - Discovery of unique or disproportionate metabolites in late development stage may cause development and marketing delays

Timeline consideration for Metabolite Safety testing

FDA

- In vitro studies should be conducted before initiation of clinical trials
  - Note that in vitro metabolic profiles of drugs are not always the same (frequently different) as in vivo
- Early in vivo animal and human metabolism studies are encouraged in drug development
- FDA encourage the identification of differences in the drug metabolism between nonclinical species and humans as early as possible
- If safety testing of a drug metabolite is warranted, studies should be completed and study reports provided to the FDA before beginning large-scale clinical trials

- *Always a good idea to communicate with the Division early*

- Keep in Mind:
  - Address metabolite issues as early as feasible
  - Case-by-case analysis
  - Communicate with the Division

199. In addition, FDA regulations provide that "[t]he clinical investigation of a previously untested drug is generally divided into three phases, and that "in general the phases are conducted sequentially." 21 C.F.R. § 312.21.

200. Celgene knew all of this. A draft internal Celgene Q&A document prepared in July 2017 stated that "[t]here is clear regulatory guidance on when such studies should be done, which was not followed."

XVI. Celgene Ignores FDA Guidance and Delays Metabolite Testing

201. Yet after the Receptos acquisition, Celgene ignored applicable FDA guidance and went ahead with large-scale, human Phase III clinical trials of Ozanimod and only later conducted the necessary Phase I metabolite testing.

202. As recounted in the Class Action Complaint, FE 21 explained that Celgene reported to the market the "sexier" efficacy findings for Ozanimod first, and then sought to backfill the results from the "non-sexy" clinical pharmacology testing that must be conducted throughout drug trials. These "non-sexy" tests examine aspects such as how a drug impacts the body or absorption rates and are typically completed during Phase I (*i.e.*, the first in-human studies). With respect to Ozanimod, however, FE 21 reported that Celgene was still undertaking many Phase I Ozanimod

studies in 2016, notwithstanding that the Company had been proceeding with large-scale Phase III clinical trials for more than a year.

203. The fact that Celgene was conducted Phase III testing on Ozanimod primed the investing public to expect that the Company was filed the Ozanimod NDA by the end of 2017. Jefferies Group LLC listed the "potential launch in MS" for Ozanimod as mid-2018. Morningstar similarly reported that Ozanimod is "poised to reach the market in 2018" and also referenced Ozanimod's "potential approval in multiple sclerosis" in 2018. An RBC Capital Markets analyst also wrote that Ozanimod was "ahead in timing."

204. Yet unbeknownst to those analysts, and the investing public, including Plaintiffs, Celgene did not begin the testing necessary to identify all of Ozanimod's metabolites until October 2016, when the Company began a "Phase I, Single-Centre, Single Dose Oral Excretion Balance Study of [14C]-RPC1063 in Healthy Male Adults," intended to "try to identify the routes and rate of removal of the study drug from the body as well as the amount of radioactivity found in blood, urine and faecal samples after a single dose." This study is referred to herein as the "Mass Balance Study."

205. The Class Action Complaint alleges that according to an October 2016 Receptos Executive Committee presentation that was sent to Martin, Celgene recognized that the work on Ozanimod was "heavily back-loaded" and would put a "[h]uge workload on [the] team with little time for delays/errors," if the Company was going to seek FDA approval of Ozanimod by December 2017. Significantly, if a new metabolite were discovered, it would imperil this target filing date.

206. According to the Class Action Complaint, this risk was discussed at the regular Ozanimod MS Team meetings that were attended by Saillot, Tran (Executive Director of Clinical

Pharmacology at Receptos), Meier-Davis (Senior Director, Preclinical Sciences at Receptos), Kao (Executive Director, Regulatory Affairs at Receptos), Thomas (Director, Regulatory Affairs at Receptos), and Skolnick (Executive Director, Clinical Development, Receptos), among others. For example, the minutes from the January 12, 2017 meeting of the Ozanimod MS Team reflected that Celgene was planning a formal risk assessment for the first quarter of 2017, and the first item to be addressed in this assessment was: "Identification of a new metabolite in the human mass balance study." As these minutes confirm, Celgene knew by no later than January 2017 that "[i]f a significant new metabolite is identified, then we will not have sufficient toxicology [studies] to support the [NDA] submission." The minutes further noted that the "[t]eam is putting a mitigation plan together to address."

207. Based on documents received in discovery, the Class Action Complaint also alleges that Celgene knew that the FDA would require full clinical study reports at the time of the NDA submission.

208. The MS NDA Submission Dashboard for the week of March 27, 2017, which, according to the Class Action Complaint, was distributed to Martin, Saillot, Kao, Skolnick, Kopicko, Martinborough, and Aranda, among others, confirmed that Celgene viewed the "[p]otential to identify a new metabolite" through the Mass Balance Study as a "key issue[]" and noted that "[p]reliminary (chromatographic) data from plasma samples in the [Mass Balance Study] is expected by the end of this week to possibly provide a clue about any potential new metabolite for [Ozanimod]."

209. A March 28, 2017 presentation sent from Zoller, Senior Director, Program Management, to Saillot stated that the "[c]urrent tox data package would not be sufficient if a new

metabolite is identified in the [Mass Balance Study]," acknowledging this as a "Potential Risk[] to the Ozanimod Submission."

XVII. In April 2017, Celgene Discovers a New Metabolite

210. In April 2017, data from the Mass Balance Study suggested two things: (i) that there was a previously unknown Ozanimod metabolite that required testing prior to seeking FDA approval; and (ii) the half-life for the metabolite was significantly longer than the half-life of Ozanimod itself. The latter, in particular, was an unwelcome development, because Celgene had promoted Ozanimod as having a competitive advantage over Gilenya because of Ozanimod's shorter half-life. As later reflected in a July 2017 Q&A document prepared by Saillot for Martin, the previously-held "assumptions around PK [pharmacokinetic] and PD [pharmacodynamics] advantages compared to other S1P modulators," like Gilenya, including "a shorter half-life and more rapid lymphocyte count recovery upon discontinuation of the drug . . . [,] will need to be updated."

211. According to the Class Action Complaint, on April 3, 2017, an Ozanimod MS Team Meeting was attended by Saillot, Skolnick, Tran, Meier-Davis, Kao, and Thomas, among others. The minutes of this meeting stated that "[c]hromatograph results from the plasma samples collected in the [Mass Balance Study] showed results that require follow-up activities, including whether this may be evidence for a metabolite that was not seen in the non-clinical studies." In light of these results, the Ozanimod MS Team was tasked with "track[ing] status of this work on a weekly basis," and a "new-cross functional team" was "established[,] led by [Martinborough] and [Meier-Davis] . . . to oversee investigation into this finding and mitigate any potential risks."

212. A presentation that Martinborough sent to Martin and Saillot following a meeting on April 24, 2017 stated the following with respect to the data from the Mass Balance Study: "It appears this new peak is real." The presentation further noted: "[W]e are assuming that it is a

single peak >10%" of Ozanimod's systemic exposure. This data signified a major metabolite that required further pharmacokinetic and toxicology testing under FDA guidance. The presentation expressly noted the possibility that Celgene would need to delay the NDA submission by eight months (to September 2018) in order to perform a non-clinical (animal) toxicology test on rodents for purposes of evaluating the metabolite for carcinogenic effects.

XVIII. Internal Realization That the Metabolite Risked a 2017 Ozanimod NDA Filing

213. On May 16, 2017, Saillot emailed Martin about the risks posed by the new data and told him to inform Defendant Smith:

> You're going to be mad at me for this one . . . Sorry. But I feel really strongly about this. You need to let Scott know. For the following reasons: In the best case scenario the December timeframe [for filing the NDA] is extremely optimistic. Anything that slows down the progress (challenges in identification of the components of the peaks, etc…) will put that timeline in jeopardy. We can leverage his being brought up to speed to ask for the mobilization of the resource[s] that we talked about to be assigned to the project. As noted below, this can be position[ed] as a heads up – That we have this finding and we need to address it in the best way (ranging from being able to explain it away, to putting this in the best context to negotiate any additional actions with the Agency) . . . .
>
> I do not see any down side. Painful as the potential bad news is shared, but better moving forward (just focusing on getting the job done and not being distracted). I can assure you that the team will not let this investigation slow down their progress (not on my watch) . . . .

214. The Class Action Complaint alleges that Martin responded to Saillot that they would discuss the issue the following day with the Receptos Executive Committee. The Receptos Executive Committee meetings were attended by Martin, Saillot, Tran, Thomas, Kao, Martinborough, Aranda, and Meier-Davis, among others.

215. In a May 30, 2017 email to Saillot, Martinborough, and Meier-Davis, among others, Tran requested additional information regarding the metabolite and "emphasize[d] the importance

and urgency of getting resolution to this issue because it could potentially require us to go back and amend the completed clinical study reports for 6 Phase 1 studies and making changes to the ongoing clinical study reports for 3 Phase 1 studies." As Tran explained: "This is a major task . . . . Most importantly, these changes could have a significant negative impact on the NDA deliverables and timeline."

216. According to the Class Action Complaint, multiple witnesses confirmed that Defendants knew that Celgene needed to further test the metabolite and examine prior studies before seeking FDA approval of Ozanimod.

217. FE 5 recalled that Defendant Tran, Receptos' Head of Clinical Pharmacology, confirmed the need for additional testing and studies of the newly discovered metabolite during an Ozanimod meeting in March or April of 2017. This meeting was attended by Martin, Saillot (who reported to Martin), Paul Frohna (Vice President of Clinical Development and Translational Medicine, Receptos, who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Darryl Penenberg (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development, Receptos, who reported to Martin), Brett Skolnick (Executive Director of, Clinical Development, Receptos, who reported to Aranda), and others. FE 5 stated that, at this meeting, Tran, who worked on the Mass Balance Study and was responsible for analyzing the metabolite and preparing the pharmacokinetic report, discussed the high amounts of the metabolite that were found in humans (but not in animals) and the need to conduct further studies. According to FE 5, Tran directed his comments to Martin and Saillot, and Martin and Saillot quickly shut down the conversation regarding the metabolite and moved on to a separate testing discussion.

218. FE 21, who had first-hand knowledge of the discovery of the metabolite, recounted that immediately after the discovery, he and others at Celgene began working on several additional studies. FE 21 characterized these efforts as "herculean" and "monumental," explaining that Celgene started new studies and went back and looked at closed findings to extract more data. FE 21 also indicated that Celgene's senior leadership was briefed on the discovery of the metabolite and the ongoing characterization efforts "quite some time before the filing" of the NDA. Furthermore, FE 21 confirmed that, over time, the team working on issues surrounding the Metabolite grew.

219. FE 21 discussed the Metabolite with his manager and stated that its discovery was of great concern. As FE 21 explained, his manager told him not to tell anyone about the metabolite finding—instead, FE 21's manager and the leader of Receptos, who other former employees have identified as Martin, would tell him who needed to know. FE 21 understood that the individual with his parallel role at Celgene and his manager's equivalent at Celgene both knew about the discovery of the metabolite. FE 21 also learned that members of Celgene's senior leadership knew about the discovery of the metabolite and received updates on the issue.

A. Celgene Lacked Long-Term Stability Data Required for the NDA

220. When submitting a new drug for FDA approval, there are guidelines recommended to be followed about the specific processes to ensure that the methods used for measuring a particular substance, such as a metabolite, are reliable and reproducible. The FDA has issued guidance on this topic. Under the heading, "Application of Validated Method to Routine Drug Analysis," that guidance states that "[a]ssays of all samples of an analyte in a biological matrix should be completed within the time period for which stability data are available." Under the heading, "Documentation," the guidance states:

> The validity of an analytical method should be established and verified by laboratory studies, and documentation of successful completion of such studies should be provided in the assay validation report. General and specific SOPs and good record keeping are an essential part of a validated analytical method. The data generated for bioanalytical method establishment and the QCs should be documented and available for data audit and inspection. Documentation for submission to the Agency should include (1) summary information, (2) method development and establishment, (3) bioanalytical reports of the application of any methods to routine sample analysis, and (4) other information applicable to method development and establishment and/or to routine sample analysis.

221. The guidance further provides that "[d]ocumentation for method development and establishment should include . . . [a] description of stability studies and supporting data."

222. According to the Class Action Complaint, on June 1, 2017, Tran emailed David Wilson, the clinical bioanalytical lead at Receptos, and asked if there would be any issue using old plasma samples from the previously conducted clinical studies to measure and analyze the metabolite as required by the FDA guidance discussed in the prior paragraphs.

223. Wilson responded that Celgene lacked sufficient long-term stability ("LTS") data to validate the metabolite for the RPC01-1001 clinical study (the "1001 Study") due to the age of the retained plasma samples collected during the study. He explained that if Celgene were to rely on metabolite data from the 1001 Study, long-term stability "becomes a real concern" as the FDA "won't consider the data as validated." As Wilson explained to Tran:

> Right off the bat, stability would be a main concern . . . . if we use . . . [the] 1001 [Study], LTS becomes a real concern. There will be some samples that you won't get validated LTS for until nearly our anticipated PDUFA time (or beyond) [*i.e.*, 12 or more months after the NDA submission]. So the agency won't consider the data as validated. If stabilizers are required in the plasma to keep the compound from converting, no existing study will work.

224. The same day, at a meeting of the Receptos Executive Committee, Tran made a presentation that included slides about the metabolite, which identified the lack of LTS data as an

issue: "Primary concern: PK sample stability. Regulatory agencies will not consider data as validated due to lack of long-term stability (LTS) data."

225. On June 6, 2017, Wilson emailed Tran:

> You had requested to know how much LTS we needed for a few studies to cover 2273 analysis. . . . Some thoughts for you:
>
> - Assuming M[ethod] V[alidation] completes in late September and we jump straight to [the] 1001 [Study], you'll need about 15 months LTS to cover this study.
> - We don't have sufficient sample volume to analyze 201A.
> - [The] 201B and 301 [Studies] will need ~4 and 3 years LTS.
> - I've added a slide to my weekly update to track this stuff.

226. As alleged in the Class Action Complaint, Celgene did not anticipate completing the "method validation" process necessary to develop and validate a method for measuring the concentration of the new metabolite until September 2017, meaning that the Company could not begin to generate the necessary LTS data until that time, at the earliest. This meant that Celgene would not be able to validate the 1001 Study until December 2018 at the earliest, and would not be able to validate the 301 and 201B Studies until September 2020 and 2021. These timelines made it impossible that Celgene would seek FDA approval of Ozanimod in December 2017.

227. In connection with an Ad Hoc Executive Committee meeting on June 15, 2017, Tran prepared a presentation titled "A Phase 1 study to evaluate PK and PD of Ozanimod and active metabolites following multiple dosing regimens (RPC01-1911)." The invitees for this meeting included Martin, Saillot, Martinborough, Aranda, Kao, Thomas, and Tran, and the presentation was sent to Martin prior to the meeting. One slide in Tran's presentation was titled "Preliminary, very limited data on new metabolite (RP112273) as of 08June2017" and stated that "RP112273 [*i.e.*, the metabolite] is pharmacologically active and more potent (> 10-fold) than

Ozanimod." The next slide stated: "RP112273 is likely the major and active moiety accountable for most of ozanimod's efficacy and/or safety." This slide further stated that "[a]dequate characterization of RP112273 PK and PD properties are required by regulatory agencies," including "Analytical information on the stability of the analyte . . . ." Tran's presentation further said that the test result must be "considered validated by regulatory (i.e., with long-term stability data)." The final slide in the presentation stated: "Note: while a validated clinical assay will be used, results are not considered validated due to lack of long-term stability data for PK samples at the time of filing" for FDA approval.

228. On July 17, 2017, Tran gave a slide presentation to the Receptos Executive Committee, which Defendant Martin led, titled "Clinical Pharmacology Strategy for RP112273 to support NDA submission and review." On a slide titled "Summary of available Clinical Pharmacology data for Ozanimod at NAD submission (Dec 2017) and during NDA review (2018)," Tran stated that Celgene would have: "Limited PK characterization of RP112273 in RMS patients (with no long-term stability data)" by December 2017.

229. Celgene also had problems with its non-clinical toxicology data for the metabolite. In a July 6, 2017 email to Meier-Davis, among others, Tran wrote that Celgene would not have "the actual human exposure until end of August/early September." Human exposure data was needed to ensure that animal studies could be appropriately extrapolated to determine safety in humans.

230. As early as July 2017, internal Celgene documents, referenced in the Class Action Complaint, reveal that the Company was discussed the possibility that lack of information and data about the metabolite could doom FDA approval of Ozanimod. A "Q&A" document from July 17, 2017 drafted by Saillot for Martin acknowledged the following in response to the question, "[w]hat

is the impact on the [NDA] submission [of the Metabolite discovery]?": "Unaddressed this would lead to a Refusal to File by FDA."

B. Celgene Seeks to Get FDA Approval to Submit the NDA Without Metabolite Data

231. As alleged in the Class Action Complaint, the July 2017 Q&A made clear that a critical aspect of Celgene's plan to address the data deficiencies stemming from the belated discovery of the metabolite was to conduct a "pre-NDA meeting" with the FDA in order to obtain agreement from the agency that the Company could provide the additional required data for the metabolite *following* the NDA submission in December 2017.

232. But under FDA guidance set forth in the agency's "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017," the FDA would need to agree to this plan; Celgene could not unilaterally delay submission of the metabolite data:

> At the [pre-NDA] meeting, the FDA and the applicant may also reach agreement on submission of a limited number of application components not later than 30 calendar days after the submission of the original application. These submissions must be of a type that would not be expected to materially impact the ability of the review team to begin its review. Any such agreement that is reached on delayed submission of application components will be summarized at the conclusion of the meeting and reflected in the FDA meeting minutes.

233. As the July 17 Q&A explained, "[t]he team is putting together a package with the available preliminary data and preparing for a meeting with FDA to negotiate submission of the NDA within the original timeframe, with agreement for additional data to be submitted during the review period [*i.e.*, after the NDA submission date] without an impact on the PDUFA action date." The Q&A noted that the "[b]est case" scenario was that the FDA would "accept submission within original timeframe," but also acknowledged the "[p]ossible scenario" that the FDA would "request

submission of additional Pharmacology and/or non-clinical safety data" with the result that the NDA submission would be "delayed by 1-2 Quarters" into the "1[st] H[alf] 2018."

234. As alleged in the Class Action Complaint, Saillot, Thomas, and Kao were already working on draft language for the pre-NDA meeting request as early as July 5, 2017. This draft language establishes that Celgene believed it would not have sufficient data by Celgene's NDA submission target date of December 2017 and would need to seek the agency's permission to submit the data after the NDA submission. Kao wrote to Saillot and Thomas: "As we discussed, here is some wording that we could consider to include in the Mtg Request Doc":

> PURPOSE OF MEETING. . . . Celgene is also seeking FDA feedback and agreement on our proposed plans for the nonclinical qualification and PK/PD characterization of 112273, a recently-identified, active major metabolite of Ozanimod. Specifically, Celgene would like to obtain FDA confirmation that it would be acceptable to provide certain data regarding 112273 during the NDA review period without delaying the PDUFA performance goal date, on the basis that Phase 3 clinical trial data are already available and support the safety and efficacy of Ozanimod in RMS patients.

C. Martin Tells Curran About the Required Metabolite Testing

235. On July 25, 2017, Martin sent an email to Curran stating that the Mass Balance Study "revealed a new disproportionate metabolite RP112273 which was not previously detected in preclinical species." Martin wrote that "[a] lot of work remains to be done in a very short period of time in order to keep the submission on schedule." He also explained that "the human mass balance study is typically conducted early in drug development, so that results are available prior to the start of Phase 3 and non-clinical carcinogenicity studies," but that an "Ozanimod human mass balance study had not been conducted at the time of due diligence" for Celgene's acquisition of Receptos. Martin continued:

> The potential risk of new metabolite(s) was identified by the team in December 2016 and tracked by the team . . . . As per FDA guidance on safety testing of metabolites (2016), metabolites

> present at disproportionately higher levels in humans than in any of the animal test species should be considered for (non-clinical) safety assessment. Human metabolites that can raise a safety concern are those formed at greater than 10 percent of parent drug systemic exposure at steady state. Since RP112273 is the major (<10-fold higher in exposure compare[d] to the parent ozanimod) and pharmacologically active, adequate characterization of Clinical Pharmacology properties of RP112273 is required by regulatory agencies.

236. Martin's email also stated that one of the "[n]ext steps" was a pre-NDA meeting in early November." Martin forwarded this email to Defendant Smith later the same day.

D. Celgene's Consultant, Among Others, Recognize That an Incomplete NDA Would Result In A Refusal To File

237. According to the Class Action Complaint, on August 1, 2017, Wilson sent Tran a slide deck with updated information on the amount of long-term stability data that Celgene needed to cover the samples from several Phase I and Phase II clinical pharmacology studies. According to Wilson, Celgene needed between approximately one and three years of that data to cover the samples from these studies—data that Celgene would not have by December 2017 when it planned to submit the NDA.

238. On the same day (August 1, 2017), Dr. David Jacobson-Kram, a Celgene consultant, emailed Meier-Davis that the situation Celgene was facing with respect to the Metabolite was "somewhat unprecedented." Jacobson-Kram noted that Celgene was "dealing with a very conservative division" at the FDA and that the division may require Celgene to demonstrate an adequate exposure of RP112273 "in all species tested" (*i.e.*, a multiple that exceeded that in humans)—yet Celgene could not demonstrate such coverage for several non-clinical toxicology tests.

239. As recounted in the Class Action Complaint, in or around August 2017, FE 21 discussed with his colleagues the likely outcome of the Celgene's decision to file the NDA without

the full results of the additional Metabolite testing. Specifically, FE 21 and his colleagues concluded that Celgene would receive an Refusal to File letter due to the absence of the requisite test results. As FE 21 explained, the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them. FE 21 shared his concerns with his direct management. FE 21 and his colleagues also discussed the likelihood that Celgene would blame Receptos personnel and the clinical pharmacology team for the RTF, and there would be massive layoffs as part of the fallout. As FE 21 stated, he and his colleagues were concerned that an RTF would cause "heads to roll locally and up top at Celgene."

240. As alleged in the Class Action Complaint, beginning in early August 2017, Martin, Saillot, Kao, Backstrom, and Lamb, among others, participated in regular "touch base" teleconferences to discuss the progress of the Ozanimod NDA submission.

241. On August 7, 2017, Tran and several other Celgene employees published a paper sponsored by Celgene in the *Journal of Clinical Pharmacology in Drug Development* entitled "Cardiac Safety of Ozanimod, a Novel Sphingosine-1-Phosphate Receptor Modulator: Results of a Thorough QT/QTc Study." In this paper, Tran stated: "Metabolism studies in animals identified 3 pharmacologically active metabolites (RP101988, RP101075, and RP101442) that have similar S1P selectivity and potency in vitro to ozanimod" and described the characteristics of these three metabolites. The article also included a Figure 1 that purported to identify the "Chemical structures of ozanimod and its active metabolites." But Tran's paper scrupulously did not mention the newly discovered metabolite (RP112273) or the requisite additional testing Celgene needed to perform as a result of that newly found metabolite.

242. The Class Action Complaint alleges that on September 18, 2017, Wilson sent Tran a slide presentation with updated long-term stability calculations for the previously conducted studies of Ozanimod. Wilson's presentation made clear that Celgene would not have all of the required long-term stability data for another five years:

Study	Amount of Data Needed	Completion Date
Study 1906	384 days	August 13, 2018
Study 1904	508 days	December 15, 2018
Study 1908	~1.5 years	~January 2019
Study 1905	~1.75 years	~March 2019
Study 1902	~2 years	~June 3019
Study 301	~3 years	~January 2020
Study 201B	~4 years	~July 2021
Study 201A	~5 years	~August 2022

243. In a September 19, 2017 email, Tran provided Meier-Davis and Martinborough with the updated human exposure value for the metabolite. According to this new data, the human exposure for the metabolite was 155,716 pg*h/mL, compared to the July 6, 2017 estimate of 75,410pg*h/mL. According to the Class Action Complaint, this updated exposure data was particularly significant as the near-doubling of the human exposure value reduced the non-clinical multiples for the toxicology by nearly half, thereby elevating the risk that Celgene would not have adequate exposure levels of the metabolite—*i.e.*, a multiple of 1.0 or greater—for purposes of the non-clinical toxicology tests.

XIX. Celgene's Unsuccessful Attempt to Get the FDA to Agree to Accepting Delayed Testing Results

A. Celgene Prepares a Flawed Briefing Book For the FDA

244. As alleged in the Class Action Complaint, on October 19, 2017, Lamb forwarded to Florence Houn, Vice President of Global Regulatory Science at Celgene, a copy of the draft

"briefing book" that is customarily submitted to the FDA in advance of the scheduled pre-NDA meeting with the goal of reaching agreement with the FDA on the planned course of action for submitting the NDA. The briefing book set forth Celgene's plan to submit certain data regarding the metabolite after the target NDA submission date of December 2017 because the data would not be available at the time of submission.

245. In his email, Lamb stated: "Personally, I don't feel the package is ready for submission and requires substantial rework." After reviewing the document, Houn provided her comments, noting: "I don't see the rationale for the delayed metabolite characterization submission by 4 months with the other late submissions."

246. In a separate October 19, 2017 email, Reiss, Corporate Vice President, Head of I&I Clinical Research and Development, provided his comments on the draft briefing book to Aranda, which were subsequently forwarded to Palmisano, Saillot, and Tran. Reiss expressed concerns about the description of the metabolite, stating: "It seems like you are going over board to sell a concept that the FDA will not buy anyway—be careful with your credibility. . . . From my point of view this would need a lot of work. There is a lot of 'happy language' and minimizing of tolerability issues." Reiss also mentioned that "Matt [Lamb] had delivered similar comments."

B. Despite Widespread Internal Doubts, Celgene Reiterates to Investors That It Would File the Ozanimod NDA By December 2017

247. On October 26, 2017, Celgene issued a press release disclosing its third quarter 2017 results. The press release stated: "Data from the phase III SUNBEAM and RADIANCE trials evaluating ozanimod in patients with relapsing multiple sclerosis (RMS) will be presented at the MSParis2017-7th Joint European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)-American Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS)

Meeting in October. Celgene plans to submit a New Drug Application (NDA) to the FDA for ozanimod in RMS by year-end."

248. On October 26, 2017, the presentation accompanying the conference call about Celgene's third quarter 2017 results, included a slide entitled "Strong Momentum. Investing to Drive Growth Beyond 2020," that was presented by Defendant Smith, stated "Ozanimod FDA filing in RMS by YE:17" and described that as a "2017 Inflection Point[]."

C. Celgene Asks the FDA If It Could Submit Metabolite Testing Data *After* Filing the NDA

249. The next day, October 27, 2017, Celgene submitted its Ozanimod briefing book to the FDA. The briefing book stated:

> Celgene is also seeking feedback and agreement on the data for the nonclinical qualification and clinical pharmacokinetics (PK) and exposure-response characterization of RP112273, a disproportionate active metabolite of ozanimod. Specifically, Celgene would like to obtain FDA agreement that it would be acceptable, given the scope of the information included in the initial NDA, to provide additional clinical pharmacology data regarding RP112273 early in the NDA review period, on the basis that phase 3 clinical study data are already available that support the safety and efficacy of ozanimod in patients with RMS."

250. The briefing book also included the following questions for the FDA:

- Question 3: Does the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support the filing for the registration of ozanimod?
- Question 4: Does the Agency agree that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and supports the filing for the registration of ozanimod?
- Question 5: Does the Agency agree with Celgene's proposed timing for the bioanalytical [long-term stability] data package for the recently-identified major and active metabolite RP112273?

251. The "Supportive Information for Question 5" included in the briefing book set forth the timeline for Celgene to submit additional data after the anticipated NDA submission in December 2017:

> Validation report addenda will be prepared following completion of LTS assessments at intervals of approximately 1, 6, 12, 15, 18, 24, 30, and 36 months. . . .
>
> Celgene plans to provide bioanalytical data as follows:
>
> In the NDA Submission: . . . As noted above, the validation report for RP112273 . . . will not include LTS Assessments . . .
>
> By the 120-day safety update: . . . Addendum to RP112273 plasma assay validation report . . . to include . . . some ongoing LTS assessments . . . .
>
> Subsequent updates: Ongoing LTS assessments to cover required analysis . . .

D. Despite Its Open Request to the FDA to Submit Delayed Testing Results, Celgene Continues to Tell Investors That the Ozanimod NDA Will Be Filed by December 2017

252. On October 28, 2017, the day after Celgene submitted the briefing book to the FDA, the Company held an Investor Event at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis. During this event, Defendant Smith stated:

> We announced positive top line data for ozanimod and SUNBEAM and RADIANCE earlier in the year, and we've been very anxiously awaiting getting to this meeting and being in a position to really get in and dig in and talk about the data.
>
> We're tremendously, tremendously thrilled with the data and satisfied and happy when we – when you think back to over two years ago when we made this acquisition investment in what was then Receptos, and you have some idea, you have some thought about what good it might look like with the data and what's going to come out of Phase III.
>
> And as we've seen the data come out, I think it's been very, very consistent, and it's been sort of at the top end of what our belief was of what this asset could do. So, it's very, very exciting for us to be heading off from this new venture in neurology, but heading off with

> such an amazing potential cornerstone product as ozanimod is what we think is a very, very positive data.

253. During the event, Defendant Curran stated about Ozanimod: "So, very excited about the data and looking forward to filing or submitting filing by the end of the year in the U.S. and EMEA the first half of next year."

254. During the event, Defendant Martin stated: "So, the RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to EMA [for Ozanimod]. For the FDA, we are working hard as we speak to get ready to file by the end of the year and early next year for EMA."

255. On October 28, 2017, Celgene issued a press release about the Paris presentation. The press release quoted Defendant Curran as stating: "Given the totality of the data for ozanimod, we believe that the benefit-risk profile supports pursuing ozanimod as a potential new oral therapeutic option and look forward to filing regulatory submissions in the U.S. by the end of 2017 and in the EU in the first half of 2018."

256. Oppenheimer issued a report on Defendants' statements at the Paris meeting, stating: "Celgene has previously announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA, based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017."

257. The Multiple Sclerosis Association of America also reported on its website about MSParis2017:

> Researchers presented data from two large phase III trials: SUNBEAM and RADIANCE Part B, both of which evaluated ozanimod in relapsing-remitting MS, and both tested ozanimod against Avonex® (intramuscular interferon beta-1a). SUNBEAM was a one-year trial and RADIANCE Part B was a two-year trial. The primary endpoint of both trials was the annualized relapse rate (ARR); study investigators also looked at MRI measures.

> The results presented showed that ozanimod had a significant effect on decreasing the relapse rate when compared to Avonex in both trials. Furthermore, MRI measures were significantly better in the ozanimod groups. Also of importance is the fact that ozanimod significantly slowed the loss of brain volume compared with Avonex. Adverse events in the trials were low. No serious infections occurred in the treatment groups and no significant difference in cardiac events was found between the two treatments. Given these trial data, ozanimod holds promise to be a new option for MS treatment that is effective, with favorable risk and side-effect profiles.

E. Continued Internal Doubts That the FDA Will Agree to Celgene's Delayed Testing Request

258. On November 13, 2017, Saillot emailed Dr. James MacDonald, a consultant retained by Celgene to give advice regarding the non-clinical issues surrounding the metabolite. Saillot provided MacDonald with a "run-down of the ongoing activities" regarding the metabolite testing and the draft NDA submission. Saillot stated: "The bottomline anyway will be whether FDA buys our 'total active structurally similar' approach . . . and if not and they require more [nonclinical] tox[icology] work, whether a post marketing commitment will suffice. Some folks mention that FDA's willingness to accept post-marketing commitment for these types of issue[s] is less than in the past."

259. As alleged in the Class Action Complaint, on November 16, 2017, Saillot provided MacDonald with a copy of the previously-submitted briefing book. Saillot also sent MacDonald a copy of the draft Toxicology Written Summary for the NDA submission and asked for MacDonald's "reactions/suggestions." Following a telephone call, Saillot followed up with MacDonald by sending him "some of the comments [he] provided on the . . . non-clinical overview" section of the NDA. In response to these comments, MacDonald emailed Saillot on November 19, 2017, stating: "The late discovery of RP112273 has had an impact on the non-clinical safety evaluation of ozanimod. A clear acknowledgement of this and the resulting

deficiencies in the package will enhance the credibility of the submission." Specifically, MacDonald noted that Celgene's claim that the nonclinical exposure multiples for the metabolite "are mostly above 1, and approach 1 . . . , which would be consistent with the ICH M3 guidance" "is the kind of argument that is a 'red flag' to me." MacDonald explained: "The simple fact is that you have no exposure multiple to this major metabolite and you should simply acknowledge that."

260. Saillot then emailed MacDonald: "None of the comments from regulatory (including me, David, Tim and Matt) recommending stating exposure multiples including RP112273 and making the conclusions of each section consistent with the wording of the label have been taken into consideration . . . . The current text and positioning is at best confusing and at worse misleading and lacks credibility. I am now at a stage where I am very concerned about the approvability of the NDA unless these issues are addressed."

261. On November 15, 2017, Jacobson-Kram, another consultant retained by Celgene, provided his "thought on the kind of issues one might expect FDA to raise" to Meier-Davis, who in turn forwarded this feedback to Martin, Saillot, Tran, Thomas, Aranda, Kao, Skolnick, and Martinborough, among others. Jacobson-Kram also had concerns about the deficient exposure multiples for the non-clinical toxicology studies:

> T]he [ICH M3(R2)] guidance was designed to assure safety of metabolites of the API. In this particular instance RP112273 represents the overwhelming majority of drug related material and is responsible for the overwhelming majority of pharmacological activity. ICH M3(R2) states: 'In some cases, for example when a metabolite composes the majority of the total human exposure, it is appropriate for exposure to the metabolite in animals to exceed that in humans (see also Question 12). In this latter case it is important to achieve a higher exposure to the metabolite in animals because this metabolite constitutes the bulk of human exposure.' However, in the case of the rat carcinogenicity study and the segment 2 reproductive toxicology studies [Celgene] has less than the clinical [*i.e.*, human] exposure for RP112273. Does the sponsor consider RP112273 to have [been] adequately tested in these studies?

262. Jacobson-Kram noted that this question was among the "major push back that you can expect from FDA."

263. The FDA maintains a Priority Review Voucher ("PRV") program designed to encourage the development of drugs to fight tropical diseases and rare pediatric diseases, as well as to counteract biological, chemical, radiological, or nuclear agents. Under the PRV program, if a company develops a drug that is voucher-eligible and approved by the FDA, the FDA may award that company a PRV. Crucially, the company is permitted to sell the PRV to another company, which may then use the PRV to speed review of any future drug submission, regardless of whether that future drug is voucher-eligible.

264. On November 20, 2017, Lamb emailed Curran:

> If . . . following the pre-NDA meeting, the FDA makes a strong recommendation that we shouldn't submit the NDA until we have all the information on the metabolite available and we decide to wait until March-April 2018 to submit the NDA, then I think it is fair to utilize a PRV [Priority Review Voucher]. This would allow for an approval in a similar time frame as if we had submitted the NDA in Dec[ember 2017].

265. Six minutes later, Curran responded to Lamb: "Agree."

266. In a separate email to Martin, Curran, and Saillot that same day, Lamb wrote:

> We've been approached about the potential sale of a Priority Review Voucher (PRV). . . . If . . . under the situation where the review division makes a strong recommendation to only submit the NDA when the additional information on the metabolite is available and the team decides to wait until early next year to submit, I think it would be fair to consider [ ] a potential priority review . . . . Do you agree? If yes, and if FDA makes it clear what we should only submit once we have the complete metabolite information included in the NDA, it would be good to gauge the division's preliminary thoughts about the merits of a priority review . . . . this could then inform thoughts around the use of a PRV.

267. Saillot responded to Martin, Curran, and Lamb later that day:

> I must say that the team had discussed the option of trying to negotiate a priority review based on the same elements you highlight below in case the FDA were to ask us to delay the filing. . . . The writing of the briefing book was along these lines (addressing an unmet need), but short of mentioning the priority review. . . . I believe the highest risk is in our non-clinical safety argument (particularly the carcinogenicity). I am not sure how a priority review would best play in that scenario . . . .

268. That same day, Curran wrote to Smith: "We have been approached about the opportunity to purchase a Priority Review Voucher (PRV). In the situation that the FDA doesn't accept the proposed Ozanimod strategy it would potentially enable us to keep the current timeline. The team is working up some scenarios to assess the value over Ozanimod's lifetime."

F. The FDA Rejects Celgene's Request to File the NDA Without Metabolite Testing Data

269. In advance of the November 27, 2017 meeting with the FDA about the briefing book for Ozanimod, the agency provided its Preliminary Meeting Comments to Celgene on November 21, 2017.

270. In response to Celgene's Question 3 ("Does the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support to the filing for the registration of Ozanimod?"), the FDA responded:

- "You should ensure that all circulating major human metabolites (i.e.,≥ 10% of total circulating drug-related material) have been adequately assessed in the nonclinical studies . . . ."
- "[Y]ou will need to ensure that adequate exposure to RP112273 was achieved in a full battery of nonclinical studies, including chronic toxicity, reproductive and developmental, and carcinogenicity studies, in two species.
- "We note that most of the plasma exposure data in animals for metabolite RP 112273 are estimated . . . . You will need to provide toxicokinetic data to document that RP 112273 has been adequately assessed in the nonclinical studies.

271. In response to Celgene's Question 4 ("Does the Agency agree that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and support the filing for the registration of Ozanimod?"), the FDA responded:

> No. A complete clinical pharmacology package, including all relevant PK and PD studies and population PK and ER analyses is required at the time of submission. We note that multiple dose (steady state) PK evaluation of the major active metabolite RP112273 will be based on study RPC01-1001. You propose to submit an abbreviated clinical study report (CSR) of study RPC01-1001 at the time of NDA submission. Full CSRs (including the bioanalytical and validation reports) for this study and all relevant clinical PK and PD studies are needed at the time of the NDA submission. Please refer to the FDA Response to Question 10, Type C meeting, March 2, 2017.

272. In response to Celgene's Question 5 ("Does the Agency agree with Celgene's proposed timing for the bioanalytical data package for the recently-identified major active metabolite RP112273?"), the FDA responded:

> Include the Validation and Analytical Study Reports for all major metabolites in the CSRs for all relevant PK and PD studies. These reports must be available at the time of the NDA submission.
>
> State whether fresh or retained plasma samples were used to quantify RP112273 in the relevant clinical studies, including RPC01-1001, RPC01-1904, RPC01-1906, RPC01-301, and RPC01-201B). If you used retained plasma samples to quantify RP112273 in the relevant Phase 1 studies, you will need to provide evidence that demonstrates the stability of RP112273 in human plasma at the time of the NDA submission.

273. The same day, Celgene received the Preliminary Meeting Comments, Tran sent an email to Wilson with the subject "Urgent - FDA response," asking Wilson "when he could talk . . . regarding the response." The next day, November 22, 2017, Tran asked Wilson "how much (if any) [of the data] in [Studies] 1904 and 1906 would be within the validated LTS" at the time of the submission. Wilson responded: "None of the 1904/1906 are within stability. We need between

a year to almost 2 years to cover the studies." In a follow-up email, Tran asked Wilson to "create a table showing the required LTS and when [Celgene would have the LTS data] for each of these studies." According to the Class Action Complaint, the table that Wilson created for Tran showed that Celgene needed between 382 and 1162 days of LTS data to cover the 1904, 1906, 1001, and 201B Studies.

274. After receiving the FDA's Preliminary Meeting Comments, Saillot emailed Martin and Tran on November 22, 2017, asking whether they should go forward with the November 27, 2017 meeting with the FDA. Saillot ran through the FDA's directives in his email, stating: "Question 3: No need for discussion – Feedback from Agency is clear . . . . Question 5-7: No need for discussion – Feedback from Agency is clear." Saillot also confirmed that his "first reaction was we did not need a [pre-NDA] meeting" with the FDA given the clarity of the feedback. Tran weighed in expressing concern over whether a meeting with the FDA would "help or hurt," suggesting that meeting with the FDA likely would prompt further negative commentary from the Agency and/or a prohibition from filing the NDA by year's end. As a result, Celgene cancelled the face-to-face pre-NDA meeting with the FDA that had been scheduled for November 27.

275. On November 27, 2017, Lamb asked Houn to review the FDA's Preliminary Meeting Comments, noting that he was assembling a "tracker" document to "help capture key gaps/challenges/etc related to the submission to ensure there is improved transparency and understanding of what will be included in the submission" and that he had "told Philippe [Martin] last week that [he] wanted to work on such a document . . . ." Houn responded to Lamb that the FDA's Preliminary Meeting Comments were "no surprise." Houn continued:

> I hope we do NOT submit without all the info as the risk for RTF is real. FDA has warned us. An RTF letter would state: "… on Nov. 21, 2017, we stated you must submit these data with the NDA…" . . . . In the grid, I recommend changing "Potential RTF issue" to

> "RTF issue." The FDA used "must submit with the NDA" for the missing info. . . . I know this is a company disappointment but hopefully we don't compound our situation.

276. According to the Class Action Complaint, Houn testified in the Class Action that in addition to Lamb, she discussed her concerns about the NDA submission with Backstrom, Celgene's Chief Medical Officer.

277. On November 28, 2017, after receiving Houn's comments, Lamb emailed Backstrom and Palmisano, Corporate Vice President, Clinical Pharmacology:

> Attached is a document that I have started to populate outlining data gaps, potential review challenges that could impact labelling and/or approvability and potential refusal to file concerns for the upcoming ozanimod RMS submissions. Creation of this document follows a number of discussions with Terrie [Curran] with a goal of ensuring this information is appropriate[ly] captured and that franchise leadership and senior management have visibility and there is transparency leading up to the submission decision. . . . .
>
> The goal is to ensure we have as much transparency as possible around the program risks/challenges going into both the NDA and MAA submissions.

278. Backstrom responded to Lamb later that day following a discussion with Defendant Smith:

> Thank you for taking the lead on this assessment. I spoke to Scott [Smith] and informed him of our discussions and of the effort to do a risk assessment with respect to quality of the application, potential RTF issues and my recommendation that we (you and me along with Terrie [Curran]) provide this to Mark [Alles] and Scott [Smith] in advance of submitting the application. I also highlighted the value of the [Priority Review Voucher] and that this could mitigate any delay in the approval timelines if we need some additional time for the submission.

279. Also on November 28, 2017, Curran emailed Smith, attaching a copy of Lamb's tracking document and stating: "I met with a small team this morning to review the FDAs feedback

and will meet later today with the IIEC. Matt will be putting together a document . . . to document the status of the submission, and mitigation of outstanding issues. I'll update you in person."

280. On November 29, 2017, Saillot provided MacDonald with the text of the FDA's response to the nonclinical question (Question 3) from the Preliminary Meeting Comments. MacDonald responded to Saillot later that day: "An expected response from the Agency. The ominous wording I see is that the metabolite will be 'a review issue.'"

281. The next day, November 30, 2017, Saillot sent MacDonald a draft of the Nonclinical Overview section of the NDA filing for his review. MacDonald sent Saillot his comments to the draft section on December 3, 2017 and noted the following in the cover email: "The document seems to suggest that everything is OK and the [compound] and metabolites have been well characterized. The data simply don't support that statement and I think it will elicit a negative response in the mind of at least the [FDA] pharm-tox reviewer." MacDonald took issue with a statement in the draft NDA filing suggesting that the metabolite has been adequately assessed in non-clinical testing, stating: "Same comment as earlier – this metabolite has not been adequately evaluated by conventional rules of engagement and I believe this will elicit a negative response." He elaborated that the metabolite had not been qualified due to the inadequate exposure multiples for the toxicology tests and rejected Celgene's representation to the contrary: "Not sure how you [can] say this as the E[xposure] M[ultiple] in the carc and reprotox studies is <1 – ?" Saillot forwarded MacDonald's comments to Martin later that day. Meanwhile, MacDonald subsequently forwarded his response to one of his colleagues, stating that "Jean-Louis [Saillot] and Receptos have a problem—but their FDA/draft NDA docs only show an 'arm-waving' approach to dealing with the problem. Not the sort of client we want to be spending this much time with!"

282. On November 30, 2017, Lamb emailed Saillot, Backstrom, Tran, Kao, and Palmisano:

> If we have almost 4-month stability at the time of NDA submission and amend the application during the review around the 8 month time point with additional data, we will have roughly 12-month sample stability in the NDA to support the RP112273 results from the impacted studies. Do we have a gap with samples from some studies being older than the stability that will be in the NDA and if so, which specific studies are impacted?

283. In response to Lamb's email, Tran summarized the long-term stability information Wilson had previously provided him on November 22, 2017, including that Celgene required over one-to-two years of long-term stability data to cover the Phase I clinical studies:

> For the NDA, [11]2273 data are presented in 3 Clin Pharm studies and the Phase 3 (exposure-response analysis). Below is the table showing the required long-term stability (LTS) for these studies. For the NDA, we have 4-month stability data. We plan to generate LTS data for 6, 12, 18, 24, 36, and 48 months on an ongoing basis.

Study	**Maximum Samples Storage (Days)**	**When RP112273 LTS Ready**
RPC01-1904 (hepatic impairment)	508	Dec-2018
RPC01-1906 (renal impairment)	382	Aug-2018
RPC01-1001 (PK in RMS)	393	Aug-2018
Phase 3 RPC01-201B, RPC01-301	1162	September 2018

284. On December 13, 2017, Michael Faletto, Celgene's Executive Director of Regulatory Knowledge and Insights, circulated to Houn, Lamb and others the FDA's draft guidance titled, "Refuse to File: NDA and BLA Submissions to CDER." Faletto noted in his cover email that "[g]iven the frequent discussions on potential for RTF, including asking the FDA at the pre-submission meeting, it would be good for all leads to familiarize themselves with these requirements." The draft guidance had been issued on December 1, 2017.

285. As with the guidance that was in place prior to December 1, 2017 discussed above, the draft guidance provides that: "When discussing the planned submission of these applications at a presubmission meeting, the FDA and the applicant reach agreements regarding the content of a complete application for the proposed indication(s) as well as agreements, if any, on submission of minor components that may be submitted not later than 30 calendar days after submission of the original application." The guidance continues: "Unless the applicant and the FDA have agreed at the presubmission meeting to delayed submission of certain components of the application, the FDA expects applications to be complete at the time of submission."

286. The next day, December 14, 2017, Faletto followed up on his prior email by circulating to the same recipients the CDER Manual of Policies and Procedures, Good Review Practice: Refuse to File. This manual outlines the policies, responsibilities, and procedures for the FDA's Office of New Drugs staff to follow when determining whether there is a basis to refuse to file a new drug application (NDA).

287. The manual provided:

> When discussing the planned submission of these applications at a presubmission meeting, the FDA and the applicant make agreements regarding the content of a complete application for the proposed indication(s) as well as agreements, if any, on submission of certain minor components that may be submitted no later than 30 calendar days after receipt of the original application. Applications are expected to be complete as agreed upon by the FDA and the applicant at the presubmission meeting. Incomplete applications, including applications with minor components not received within 30 calendar days after receipt of the original application, as agreed at the presubmission meeting, will be subject to an RTF decision.
>
> The following policy statements emphasize CDER's expectation that applications are to be complete at the time of submission and that a piecemeal approach to building a complete application through amendments following initial submission is unacceptable. . . . .
>
> CDER staff will refuse to file:

> Materially incomplete or inadequately organized applications that would not permit timely, efficient, and complete review by all relevant disciplines . . . .

288. The manual also cited several "examples of complex and significant deficiencies that may provide support for an RTF action," including: "Failure to provide bioanalytical method validation"—*i.e.*, long-term stability data."

XX. Celgene Files the NDA Despite the FDA's Rejection of the Delayed Testing Approach

289. Despite the FDA's feedback to Celgene making it clear that the agency would not agree to the Company's plan to file for Ozanimod approval despite lacking complete data for the metabolite, Celgene barreled forward with its plan to file the NDA by the end of 2017. Celgene embarked on this path without disclosing to the investing public, including Plaintiffs, that it posed acute risks that the FDA would issue a Refusal to File.

290. As alleged in the Class Action Complaint, FE 22 confirmed that Celgene moved forward and submitted the Ozanimod NDA without the required data in December 2017. FE 22 explained that one of the additional metabolite studies was underway in December 2017, but results of that study were not to be received until April 2018—four months after the Company's self-imposed filing deadline. FE 22 had heard that Martin and Saillot "just wanted to get the NDA out the door." FE 20 echoed FE 22's account, explaining that the Ozanimod NDA had been "hustled forward."

291. The Class Action Complaint includes allegations that many of Celgene's high-ranking employees were entitled to receive bonuses based on the submission of Ozanimod NDA to the FDA (regardless of whether the FDA had approved the drug). FE 22 recounted that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. FE 20 similarly confirmed that the compensation for Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing. FE 20 explained that this was the "carrot" for the

employees, and the higher one went up the corporate chain, the greater the amount of compensation tied to the NDA filing.

292. According to the Class Action Complaint, FE 21 stated that he and his colleagues disagreed with Celgene's decision to push forward with the NDA, instead believing that the Company should wait and finish all of the necessary testing and other work before submitting the NDA. He explained that he and his colleagues could not understand why the Company would not invest the additional time to perform the necessary testing prior to submitting the NDA, especially when an RTF letter, which results from a deficient NDA filing, could severely damage Celgene's reputation. According to FE 21, there was no empirical reason for pushing ahead with the deficient filing. When FE 21 shared his thoughts with his managers, he was told to keep his views to himself.

293. On January 8, 2018, Celgene issued a press release, filed on Form 8-K with the SEC that identified the "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)" as a "2018 Expected Operational Milestone[]."

294. The Company highlighted other testing results in a January 25, 2018 Form 8-K, but made no mention of the metabolite and the further Phase I testing required for FDA approval, stating: "In December, a New Drug Application (NDA) was submitted with the FDA for ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE Part B and SUNBEAM trials evaluating ozanimod in patients with RMS."

295. On February 7, 2018, Celgene filed its Annual Report on a Form 10-K with the SEC ("2017 10-K"), again representing that "a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS based on data from the phase III trials evaluating Ozanimod in patients with RMS." The 2017 10-K also included a chart representing that the "Status" of

Ozanimod for RMS was "Regulatory submission" and that Celgene "Entered current status" in the fourth quarter of 2017. The 2017 10-K did not mention the metabolite or the need for further testing.

XXI. The FDA Issues a Rare Refusal To File Letter For Ozanimod

296. On February 27, 2018, Celgene disclosed that it had received a Refuse to File letter from the FDA in response to its Ozanimod NDA submission.

A. Celgene's NDA Found Facially Deficient For Numerous Reasons

297. The RTF letter began: "After a preliminary review, we find your application insufficiently complete to permit a substantive review. Therefore, we are refusing to file this application . . . ." The letter then went on to list both Clinical Pharmacology and Nonclinical deficiencies.

298. Under the heading "Clinical Pharmacology," the RTF letter stated:

> ***The long-term stability of RP112273, a recently identified predominant and active metabolite of ozanimod, has not yet been established.*** Retained plasma samples were used to quantify RP112273 in studies RPC01-201 (Part A and B), RPC01-301, RPC01-1904, RPC01-1906 and for most of subjects in study RPC01-1001. The samples were analyzed outside of the long-term stability window (136 days) for RP112273, and more than one year after collection for some of the samples. Long-term stability evaluations for RP112273 are ongoing. Per the Guidance for Industry on Bioanalytical Method Validation (2013), "Assays of all samples of an analyte in a biological matrix should be completed within the time period for which stability has been demonstrated". Because of the above issue, the clinical pharmacokinetics of RP112273 have not been adequately characterized. The results of the pharmacokinetic analyses for RP112273 will inform critical assessments related to Zeposia dosing, e.g, the need for dosing adjustments for intrinsic or extrinsic factors that might affect the pharmacokinetic or pharmacodynamics of ozanimod. Without such information, labeling cannot be written to inform drug use in specific populations or patients taking concomitant medications.

299. Under the heading "Nonclinical," the RTF letter stated:

> RP112273, an active metabolite with potency at the S1P 1 and 5 receptors similar to that of the parent compound, accounts for the majority . . . of drug-related material in circulation in humans. Therefore, you will need to demonstrate that RP112273 has been assessed in a standard battery of nonclinical studies. To bridge to the existing nonclinical data, you would need to demonstrate adequate plasma RP112273 exposures in males and females, using the same dosing regimens used in the pivotal studies, in all species tested. Based on a preliminary examination, the available TK data are insufficient to allow a determination of the adequacy of the safety assessment for RP112273.

300. According to a February 15, 2021 paper published in *JAMA Internal Medicine*, "Contents of US Food and Drug Administration Refuse-to-File Letters for New Drug Applications and Efficacy Supplements and Their Public Disclosure by Applicants," between January 1, 2008, and December 31, 2017, the FDA received 1,180 NDAs. Of those applications, 73 (6.2%) received RTF letters. Thus, as that paper noted, RTF letters are "rare."

301. As William Blair stated in a report entitled, "While Not a Crisis for Ozanimod, FDA's RTF Letter Represents Another I&I Franchise Setback and Could Lead to a One-Year Delay": "In our view, well managed and high quality large-cap biotech companies do not make execution mistakes like the one disclosed on Tuesday" by Celgene. The report added: "Obviously, investors are frustrated by another setback in the autoimmune franchise, especially in light of late last year's mongersen failure in Crohn's disease, clinical delay for ozanimod in ulcerative colitis, and soft third-quarter sales for Otezla."

302. Leerink Partners noted in a report entitled "How Many Self Inflicted Wounds Are Excusable? Ozanimod Delay at Least a Year," that the RTF "only adds to investors' growing unease with [Celgene]'s direction and oversight of key activities" and stated that "the company clearly made a decision to file this application at risk, despite late information that might have been more thoroughly disclosed and explored in the application, had the filing been postponed by a few months." As Leerink Partners further explained:

> Celgene appears to have gambled on the ozanimod filing in December 2017 while knowing about the unanticipated finding from a late-stage clinical pharmacology trial [*i.e.*, the Mass Balance Study] after the two phase IIIs read-out successfully. This study seemed to duplicate the type of study that would originally have been completed by Receptos, and the completion of the study itself suggests some recognition of a deficiency in the early clinical package prepared by the prior owner.

B. Following Disclosure of the RTF, Celgene's Stock Declines

303. Following Celgene's disclosure of the RTF letter, the price of the Company's common stock declined from a closing price of $95.78 per share on February 27, 2018 to a closing price of $87.12 per share on February 28, 2018.

C. Internal Discussions Confirm That the RTF Was Not a Surprise

304. In a February 27, 2018 email to Backstrom and Palmisano, Lamb re-forwarded Tran's LTS chart from November 30, 2017, stating:

> Some of the studies are complete but we don't have the required sample stability for the RP112273 metabolite. Please see the below table which provides dates for when we will have the required sample stability for some of the Clin Pharm studies in 2018. In the table you will see that we won't have the required stability data for the phase 3 samples until 2020. This is part of the equation. Once we have the stability data, we can consider the studies as "valid" as it relates to us having going back and used retain[ed] plasma samples for the RP112273 characterization.

305. In the same email, Lamb also wrote:

> FDA didn't agree to anything and they[]stated repeatedly that the CSRs [clinical study reports], BARs and stability data needed to be in the original submission. Even in a subsequent email exchange FDA stated reports needed to be submitted at . . . the time of the NDA submission (not within 30 days which we proposed via email).

306. In a February 27, 2018 email to Palmisano, Tran wrote: "[T]he FDA wanted LTS data and would not accept those during the NDA review. In the pre-NDA feedback, the FDA

specifically requested LTS data for studies 1001 (PK/PD in RMS), 1904 (hepatic impairment) and 1906 (renal impairment)."

307. On March 15, 2018, Faletto asked Lamb if he would address the audience at an upcoming Celgene Regulatory Affairs meeting. Lamb responded: "I will be happy to speak to ozanimod and the RTF in the opening and try to answer any questions folks may have. There isn't much to learn from a Regulatory Affairs perspective. FDA repeatedly stated what they expected, it was ignored and we got a RTF."

308. On or about April 3, 2018, a presentation prepared by Backstrom and his team describing the circumstances leading to the RTF was given to the Board of Directors. One of the presentation slides, entitled "Ozanimod-Related Correspondence with the FDA," stated: "Feb 2018: . . . FDA issues Refusal to File Letter, identifying nonclinical and clin pharm deficiencies consistent with the pre-NDA meeting feedback."

309. As alleged in the Class Action Complaint, Defendant Smith, who had been promoted from head of I&I to Chief Operating Officer in April 2017, was forced out of Celgene in April 2018. George Golumbeski, Celgene's head of business development, who was lauded as the chief architect of Celgene's acquisition strategy, also left the Company in April 2018. In addition, Defendant Martin was relieved of his responsibilities at Receptos in June 2018 and, according to FE 22, the employees within Martin's command at Receptos were let go after Celgene received the RTF.

310. On April 25, 2018, several scientists gave a presentation at the American Association of Neurology ("AAN") 2018 Annual Meeting in Las Vegas, Nevada entitled "Safety of Ozanimod Versus Interferon β-1a in Two Multicenter, Randomized, Double-Blind, Parallel-Group, Active-Controlled, Double-Dummy Phase 3 Studies in Relapsing Multiple Sclerosis

(SUNBEAM and RADIANCE Part B)." This presentation, which was partially funded by Celgene, disclosed to investors certain specifics of the Metabolite, dubbed CC-112273 by the Company, stating that: "Ozanimod is metabolized in humans to form one major active and other minor active metabolites"; "CC112273 accounts for the majority of the total activity of ozanimod in humans"; and "CC112273 is a minor metabolite in animal species."

D. Morgan Stanley Discloses That the Refusal To File Will Delay Ozanimod Approval For Years and Celgene's Stock Drops Again

311. On April 29, 2018, Morgan Stanley published a report entitled "More Bread Crumbs Yield Less Confidence In Ozanimod" that provided a detailed analysis comparing the recently disclosed information regarding the metabolite to the data from the Company's earlier pre-clinical studies involving Ozanimod's other metabolites. This analysis demonstrated that Celgene would need to run additional pre-clinical toxicology studies, which could take six months to two years. Thus, when combined with the time needed to start the studies, produce the study results and refile the NDA, these additional studies would result in a total delay of one to three years.

312. In response to the news of a further delay, Celgene's common stock fell from a closing price of $91.18 per share on Friday, April 27, 2018 to a closing price of $87.10 per share on Monday, April 30, 2018, the next trading day.

313. During its first quarter 2018 conference call on May 4, 2018, Celgene confirmed that the RTF arose as a result of the metabolite, which Celgene had belatedly discovered the through the Mass Balance Study in November 2016. Backstrom stated, in part: "[T]he key issues for the Refusal to File centered on the completeness of the clinical pharmacology and the nonclinical portions of the NDA. These issues relate to the major active metabolite, CC-112273." Specifically, Backstrom stated that Celgene conducted "a radio-labeled human mass balance

study" that "identified CC-112273 as a major metabolite, accounting for approximately 90% of the activity" and that CC-112273 "disproportionately formed in humans and was not identified as a major metabolite in the nonclinical [i.e., animal] pharmacology studies." Backstrom further revealed that the half-life of the metabolite is ten to thirteen days, compared to the previously reported Ozanimod half-life of nineteen hours, which was one of its key competitive advantages over Gilenya.

314. Celgene disclosed that, upon review of the Ozanimod NDA, the FDA "requested further characterization of CC-112273." Alles claimed to be surprised by the FDA's decision, stating that: "[T]he hindsight view is that the characterization of [the] metabolite was something that we simply underestimated in the context of FDA's decision." As alleged in the Class Action Complaint, FE 2, stated that, based on his experience with more than five NDA submissions, it was "incomprehensible" that Celgene was surprised by the FDA's interest in the metabolite.

315. An *In the Pipeline* article published after the May 4, 2018 conference call, entitled "Finger-Pointing at Celgene," asked "why wasn't [the metabolite] issue fully addressed for the FDA?" and stated:

> Analyzing blood levels of the parent compound and metabolites is one of the biggest points of Phase I, actually, so it's not like this could have been overlooked. If you find out that what you thought was your drug is apparently just a prodrug for what's really working *in vivo*, well, you have more work to do. But it appears that lack of data about the metabolite could have been one of the main reasons the FDA found the NDA unworkable, which just makes no sense.

XXII. CELGENE'S CORPORATE DISCLOSURE PROCESS

316. Based on documents received in discovery, the Class Action Complaint includes detailed allegations about Celgene's corporate disclosure process for clinical development and financial performance during the relevant period:

- From at least 2016 through April 2, 2018, Celgene's quarterly disclosures in press releases, earnings calls, related investor slide presentations, and SEC Forms 10-Q and 10-K were prepared and finalized through an internal corporate process involving the Company's senior executives (the "Quarterly Disclosure Process").

- The chief participants in the Quarterly Disclosure Process included the Company's CEO, its CFO, its President and COO, the President of Hematology and Oncology, and the President of I&I.

- Defendant Smith personally participated in Celgene's Quarterly Disclosure Process at all relevant times, with responsibilities first as the President of I&I (through March 31, 2017) and then as President and COO of the Company (from April 1, 2017 through April 2, 2018).

- Defendant Curran personally participated in the Quarterly Disclosure Process as the President of I&I from April 1, 2017 through the end of the Class Period. Representatives from Celgene's legal and investor relations departments also participated.

- Celgene's Quarterly Disclosure Process entailed a joint drafting and review undertaking by Celgene's executives that followed a typical cadence in each quarter. The script for the prepared remarks for the given quarter's earnings call was drafted by the executives with speaking roles on the call. The draft earnings call script would then be reviewed and edited by other participants. This collaborative review process typically occurred over several days just prior to the given earnings call, with edits and revisions normally provided in meetings and in emails containing draft documents showing proposed edits and comments in "redline."

- To the extent information in an earnings call script related to a particular franchise, specifically including clinical development matters regarding products within that franchise, such information was provided to the Quarterly Disclosure Process by the head of the franchise. Thus, for example, if an earnings call script discussed the clinical development of an I&I product, the information regarding that topic was provided by the President of I&I. According to Defendant Smith, the President of I&I, in turn, typically obtained such information from the relevant clinical development project leader within I&I, including Defendant Martin, who headed the Ozanimod NDA project.

- In the Quarterly Disclosure Process, investor slide presentations that accompanied quarterly earnings calls and their attendant scripts were drafted, reviewed, revised and finalized concurrently and in a similar manner as earning call scripts. Members of Celgene's investor relations department typically drafted initial proposed slides and talking points. The executives in the Quarterly Disclosure Process then revised and finalized

them through a joint, iterative process in the days leading up to the day of the earnings call, reviewing drafts in meetings and emails and providing edits and comments, often in redline form. Here again, language regarding clinical development issues in a particular franchise was handled by the head of the relevant franchise.

- Defendants Smith and Curran and the other participants in the Quarterly Disclosure Process reviewed drafts of the press releases that Celgene published in conjunction with its earnings calls. From at least April 1, 2017 through April 2, 2018, Smith and Curran reviewed drafts of the press releases, provided input and comments, and participated in finalizing them. As with Celgene's other public disclosures, if a press release contained information concerning a clinical development matter within I&I, that information would be provided for purposes of the press releases by the project leaders within I&I, including Defendant Martin, who headed the Ozanimod NDA project.

- Celgene's senior management, including between April 1, 2017 and April 2, 2018, provided review and input to draft Celgene press releases, whether quarterly or released at other times, through an iterative process, reviewing drafts (often via emails) and providing edits and comments, often in redline form.

- Information was similarly provided by I&I for purposes of Celgene's Forms 10-Q and 10-K. In the Quarterly Disclosure Process, the head of I&I would review sections of the 10-Q or 10-K that related to I&I and provide comment and input. After the franchise presidents had completed their review, the draft 10-Q or 10-K would go to the President and COO as well as the CEO and CFO, for their review, and for finalization.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

317. From September 2016 to February 2018 (for Plaintiffs' common law fraud claim) and from February 2017 to February 2018 (for Plaintiffs' Exchange Act claim), Defendants made a series of materially false and misleading statements and omitted material facts about (i) the current state of Otezla's sales and the drug's ability to gain market acceptance, capture market share, and generate revenue for Celgene, including to achieve the Company's 2017 forecast for the drug; and (ii) the undisclosed discovery of a key, active metabolite of Ozanimod that required further testing, the sufficiency of that testing data, and the completeness of Ozanimod's application for FDA approval as a treatment for multiple sclerosis.

I. Defendants' False and Misleading Statements and Omissions About Otezla

318. On September 12, 2016, during a Celgene presentation at the Morgan Stanley Global Healthcare Conference ("September 12, 2016 Presentation"), an analyst asked Defendant Smith about Otezla pricing. Smith responded that "[w]e believe that we should increase price and we've to the data to support increasing utilization, and increasing value."

319. The foregoing statement was materially false or misleading at the time it was made, including because Smith lacked a reasonable basis to state, nor did he honestly believe, that Celgene should raise Otezla's price, given that Smith (i) had been pursuing a discounting strategy with respect to Otezla pricing in order to try and increase its market share; and (ii) knew that Otezla sales were having growth problems.

320. In its Schwab Motion to Dismiss Decision, the Court held that the foregoing statement was an "actionable opinion," because "beginning in 2014, Smith was repeatedly warned that the pay-to-play strategy was flawed but Smith said that he would do 'whatever it takes to get business' . . . and the I&I Executive Committee . . . of which Smith was a member was informed about the 'lack of growth in Otezla sales and its fundamental causes . . . by no later than the third quarter of 2016.'"

321. The foregoing statement is only alleged as actionable by Plaintiffs' common law fraud claim, and not their Exchange Act claim.

322. On April 27, 2017, Celgene conducted a conference call about its first quarter 2017 financial results (the "April 27, 2017 Earnings Call"). During the question-and-answer portion of the call, an analyst from UBS asked Celgene with respect to Otezla: "Can you just walk through what gives you confidence growth will bounce back or could we see continued pressure in the near term?"

323. Defendant Curran responded:

> I think there was really 3 key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased GTN [gross to net] as a result of the contracting. But importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw a minimal drawdown in inventory.
>
> Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into quarter 2, we do see the net sales rebounding and on track to deliver our 2017 guidance.

324. Defendant Curran's response to the UBS analyst's question was materially false or misleading at the time it was made, including because (i) Defendants' Otezla pricing strategy was fundamentally flawed and could never deliver the 2017 guidance disclosed by Celgene; (ii) Celgene sales representatives were reporting flat, not increasing sales, from the launch of the drug in March 2014; (iii) Otezla sales and revenue for the first quarter of 2017 underperformed internal budget forecasts and April sales (as of April 27, 2017) did not make up for the first quarter underperformance; (iv) Curran had received a presentation the day before this statement showing a 17% shortfall in internal budgeted Otezla sales for 2017; (v) during the third and fourth quarters of 2016, Curran had been explicitly warned by high-ranking Celgene employees that the 2017 guidance could not be met and should be lowered; (vi) Otezla sales prospects were hampered by insurance company step-edits, other insurance coverage issues, and inferior efficacy compared to competitor products; (vii) the overall psoriasis and psoriatic arthritis markets shrank in the first quarter of 2017 and internal Celgene forecasts, which were not disclosed to the investing public, assumed that trend would continue through year-end; (viii) Otezla's market share in both the psoriasis and psoriatic arthritis markets was either flat or declining in the first quarter of 2017 and internal Celgene forecasts, which were not disclosed to the investing public, assumed that trend

would continue through year-end; and (ix) the new PBM contracts referenced by Curran were underperforming by the first quarter of 2017. For the same reasons, Defendant Curran's response lacked a reasonable basis and was not an expression of her honestly held beliefs about Otezla.

325. In its Class Action Motion to Dismiss Decision, this Court held that Defendant Curran's response to the UBS analyst was "not [a] forward-looking discussion[]" and was "not protected by the [PSLRA] Safe Harbor." The Court also found that the response was actionable because "Curran's opinion lacked a reasonable basis and Curran did not honestly believe it," given allegations, included herein, that "Curran was explicitly warned by the third quarter of 2016 that Celgene was not going to hit its 2017 projection" and that "Curran and Smith told the forecasting team to change the internal forecasts to conceal the lack of sales growth."

326. Analyst reports discussed Celgene's reaffirmation of its 2017 Otezla guidance, including by Defendant Curran in the above statement. In an April 27, 2017 report, BMO Capital Markets stated that: "Management reiterated FY2017 Otezla sales of $1.5-1.7bn." UBS stated in an April 27, 2017 report that "Celgene reiterated confidence in achieving 2017 guidance and the longer term outlook for Otezla, citing consistent market share growth (>40% of new patients), narrowing its position behind Stelara in the psoriasis market, and new contracts that increase market access and share." A JMP Securities report issued on April 28, 2017 said: "We note that previous guidance of $1.5bil to $1.7bil in net Otezla sales for 2017 remains intact despite this soft quarter."

327. On July 27, 2017, Celgene conducted a conference call about its second quarter 2017 financial results (the "July 27, 2017 Earnings Call"). On this conference call, Defendant Curran stated that "Q2 was an outstanding quarter for Celgene I&I, highlighted by significant

sequential growth for OTEZLA. Q2 OTEZLA performance indicators continued to strengthen and market share and prescriber adoption increased significantly in both U.S. and internationally."

328. The foregoing statement was materially false or misleading at the time it was made, including because (i) Otezla market share was flat or declining, and actually declined in the second quarter and did not "increase significantly"; (ii) Defendant Curran admitted in internal emails not disclosed to the investing public that Otezla's market share was "flat" in the second quarter of 2017; (iii) Defendant Curran received presentations not disclosed to the investing public showing that a decline in Otezla market share was a key risk that could impair the Company's public Otezla guidance for 2017; (iv) "prescriber adoption" did not "increase significantly" in the second quarter of 2017; (v) PBM contracts had underperformed Celgene's internal forecasts in the second quarter of 2017; and (vi) Otezla sales had underperformed Celgene's internal forecasts for the first half of 2017. For the same reasons, to the extent that the foregoing statement is construed as an opinion expressed by Defendant Curran, it lacked a reasonable basis and was not an expression of her honestly held beliefs about Otezla.

329. In the Class Action, Defendants opposed the addition of the foregoing statement to the Third Amended Complaint only on the basis of prejudice (which is inapplicable here), thereby implicitly conceding that the foregoing statement was materially false or misleading when made. (*See* ECF No. 173 at 8-12.)

330. Analyst reports discussed Defendant Curran's statements during the July 27, 2017 call. In a July 27, 2017 report, SunTrust stated that: "Otezla is already benefiting from expanded coverage and showed a substantial rebound in growth (Street was expecting a miss) . . . . In 2Q17, U.S. sales growth was driven by increased prescriber adoption and market share gains (benefiting from expanded coverage) . . . ."

II. Defendants' False and Misleading Statements and Omissions About Ozanimod

331. In connection with the April 27, 2017 Earnings Call, Celgene issued and posted on its public website a slide presentation. One of the slides, entitled "2017 I&I Franchise Outlook," was presented by Defendant Smith, and contained the below graphic stating that Celgene would "submit Ozanimod U.S. NDA in RMS" in 2017:

332. Prior to presenting this slide, Smith consulted with, and received information about the Ozanimod NDA project from Defendant Martin, other senior members of the I&I franchise, and project team members from the Receptos site in San Diego.

333. The foregoing slide presented by Defendant Smith during the April 27, 2017 Earnings Call was materially false or misleading at the time it was presented, including because (i) data from the Mass Balance Study had, by April 27, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

334. In its Class Action Motion to Dismiss Decision, this Court held that "in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites, as well as specific alleged facts, Celgene's disclosure as to the NDA submission," *i.e.*, "that it would submit the NDA for Ozanimod by the end of 2017," "was materially incomplete and misleading." The

Court also found that given "FDA guidance . . . employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that the [FDA] was not going to approve the NDA without the necessary Metabolite testing results." Further, the Court stated that "[t]o make the public disclosures the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA."

335. Analysts focused on Celgene's representations that it would submit the Ozanimod NDA by the end of 2017. In an April 27, 2017 report, Barclays stated that "[n]otably, Celgene plans to submit an NDA in RMS by year-end, with a likely launch in 2018." J.P. Morgan similarly stated in an April 27, 2017 report that a "Key 2017 catalyst[]" included "Ozanimod Ph3 data in MS in May with NDA submission by YE17" and Oppenheimer wrote in an April 27, 2017 report that "Celgene announced it intends to file Ozanimod for regulatory approval by the end of 2017 using data from the phase III SUNBEAM and RADIANCE studies."

336. In connection with the July 27, 2017 Earnings Call, Celgene issued and posted on its public website a slide presentation. One of the slides, which was presented by Curran, reiterated, under the heading "Ozanimod Moving Forward," that Celgene was "[p]reparing" Ozanimod "for regulatory submission to the FDA by YE:17." Another slide presented by Curran, under the heading "Optimize the Ozanimod Opportunity," stated "File ozanimod U.S. NDA in RMS by YE:17."

337. The foregoing slides were materially false or misleading at the time when they were presented, including because (i) data from the Mass Balance Study had, by July 27, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the

required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

338. In its Class Action Motion to Dismiss Decision, this Court held that "in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites, as well as specific alleged facts, Celgene's disclosure as to the NDA submission," *i.e.*, "that it would submit the NDA for Ozanimod by the end of 2017," "was materially incomplete and misleading." The Court also found that given "FDA guidance . . . employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that the [FDA] was not going to approve the NDA without the necessary Metabolite testing results." Further, the Court stated that "[t]o make the public disclosures the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA."

339. As alleged in the Class Action Complaint, Defendant Smith, pursuant to his responsibility and authority to act as an agent of Celgene in his role as President and COO of the Company, including through the quarterly disclosure process, had ultimate authority as a matter of law over statements in the foregoing corporate slide presentation through his review, approval, and ratification of the statements. Smith received specific information regarding Ozanimod and the Metabolite in advance of July 27, 2017, from Defendant Martin, other Ozanimod project team members within I&I, and Ozanimod team members at Receptos in San Diego. Smith also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the statements after their issuance.

340. During the July 27, 2017 Earnings Call, Defendant Smith stated: "Just to add on to the comments, we feel very, very good about the data that's emerging for ozanimod and looking forward to getting it out."

341. The foregoing statement was materially false and misleading at the time it was made, including because (i) data from the Mass Balance Study had, by July 27, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File. For the same reasons, to the extent that the foregoing statement is construed as an opinion expressed by Defendant Smith, it lacked a reasonable basis and was not an expression of his honestly held beliefs about the Ozanimod data or the Ozanimod NDA submission.

342. In its Class Action Certification Decision, this Court held that the foregoing statement was "actionable" because given that "Smith was discussing the Ozanimod NDA, his failure to discuss the Metabolite and the need for additional testing was misleading." In addition, in its Schwab Motion to Dismiss Decision, this Court held that the foregoing statement was "not forward looking," because "Smith was discussing current data," "[s]pecifically, that in light of the current data, Celgene was in a good position to submit its NDA at the end of the year." The Schwab Motion to Dismiss Decision found that "when discussing clinical Ozanimod data and the NDA filing, Smith was required to fully and truthfully discuss the results."

343. During the July 27, 2017 Earnings Call, Defendant Smith presented a slide that stated "Ozanimod positive top-line data in RMS; Advancing towards FDA filing by YE:17." The

foregoing slide was materially false and misleading at the time it was presented, including because (i) data from the Mass Balance Study had, by July 27, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

344. In its Class Action Certification Decision, this Court held that the foregoing slide was "actionable" because given that "Smith was discussing the Ozanimod NDA, his failure to discuss the Metabolite and the need for additional testing was misleading." In addition, in its Schwab Motion to Dismiss Decision, this Court held that the foregoing slide was "not forward looking," because "Smith was discussing current data," "[s]pecifically, that in light of the current data, Celgene was in a good position to submit its NDA at the end of the year." The Schwab Motion to Dismiss Decision found that "when discussing clinical Ozanimod data and the NDA filing, Smith was required to fully and truthfully discuss the results."

345. On July 27, 2017, Celgene filed with the SEC a Form 8-K (the "July 27, 2017 8-K"). The July 27, 2017 8-K stated: "In May, Celgene disclosed positive top-line results from the confirmatory phase III RADIANCE™ trial evaluating ozanimod in RMS. . . . An NDA submission to the FDA based on the combined phase III SUNBEAM™ and RADIANCE™ trials for RMS is expected by the end of 2017."

346. The foregoing statement was materially false or misleading at the time it was made, including because (i) data from the Mass Balance Study had, by July 27, 2017, revealed the

existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

347. In its Class Action Motion to Dismiss Decision, this Court held that "in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites, as well as specific alleged facts, Celgene's disclosure as to the NDA submission," *i.e.*, "that it would submit the NDA for Ozanimod by the end of 2017," "was materially incomplete and misleading." The Court also found that given "FDA guidance . . . employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that the [FDA] was not going to approve the NDA without the necessary Metabolite testing results." Further, the Court stated that "[t]o make the public disclosures the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA."

348. As alleged in the Class Action Complaint, Defendant Smith, pursuant to his responsibility and authority to act as an agent of Celgene in his role as President and COO of the Company, including through the quarterly disclosure process, had ultimate authority as a matter of law over this statement through his review, approval, and ratification of the statement. Smith received specific information regarding Ozanimod and the Metabolite in advance of July 27, 2017, from Defendant Martin, in his role and as part of his responsibilities as senior manager of the Ozanimod NDA project, including the status of the NDA and the need for additional testing. Smith

also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the statement after its issuance.

349. On September 26, 2017, Celgene participated in the Cantor Fitzgerald Annual Healthcare Conference. In connection with the conference, Celgene issued and posted on its public website a slide presentation (the "Cantor Fitzgerald Presentation"). One of these slides stated that Ozanimod was "[o]n-track for NDA submission by YE:17."

350. The foregoing slide was materially false or misleading at the time it was presented, including because (i) data from the Mass Balance Study had, by September 26, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

351. In its Class Action Motion to Dismiss Decision, this Court held that "in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites, as well as specific alleged facts, Celgene's disclosure as to the NDA submission," *i.e.*, "that it would submit the NDA for Ozanimod by the end of 2017," "was materially incomplete and misleading." The Court also found that given "FDA guidance . . . employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that the [FDA] was not going to approve the NDA without the necessary Metabolite testing results." Further, the Court stated that "[t]o make the public disclosures the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA."

352. On October 26, 2017, Celgene conducted a conference call about its third quarter 2017 financial results (the "October 26, 2017 Earnings Call"). In connection with the October 26, 2017 Earnings Call, Celgene issued and posted on its public website a slide presentation. One of these slides, presented by Curran, under the heading "Ozanimod Moving Forward in Multiple Sclerosis," stated: "Preparing for regulatory submission to the FDA by year-end and EMA filing in H1:18." Curran presented another slide that stated: "Submit ozanimod U.S. NDA in RMS by YE:17."

353. The foregoing slides were materially false or misleading at the time they were presented, including because (i) data from the Mass Balance Study had, by September 26, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

354. In its Class Action Motion to Dismiss Decision, this Court held that "in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites, as well as specific alleged facts, Celgene's disclosure as to the NDA submission," *i.e.*, "that it would submit the NDA for Ozanimod by the end of 2017," "was materially incomplete and misleading." The Court also found that given "FDA guidance . . . employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that the [FDA] was not going to approve the NDA without the necessary Metabolite testing results."

Further, the Court stated that "[t]o make the public disclosures the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA."

355. As alleged in the Class Action Complaint, Smith, pursuant to his responsibility and authority to act as an agent of Celgene in his role as President and COO of Celgene, including through the quarterly disclosure process, had ultimate authority as a matter of law over the foregoing slides through his review, approval, and ratification of the foregoing slides. Indeed, Smith personally reviewed and provided comment on the draft slides and presentation scripts in the days leading up to the October 26, 2017 Earnings Call. He also received input and information related to the October 26, 2017 Earnings Call from Defendant Martin, the Ozanimod project team leader, as well as others within I&I leadership and members of the Ozanimod project team at Receptos in San Diego. Defendants Smith, Curran, and Martin also had known about the metabolite for months, as of October 26, 2017. In addition, Smith recklessly disregarded and tolerated the misrepresentation and omission of material facts in these statements after their issuance.

356. During the October 26, 2017 Earnings Call, Defendant Smith presented a slide that stated, under the heading "2017 Inflection Points with Multiple Value Drivers Delivering,": "Ozanimod FDA filing in RMS by YE:17; EU filing in Q1:18."

357. The foregoing slide was materially false or misleading at the time it was presented, including because (i) data from the Mass Balance Study had, by September 26, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene

submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

358. In its Schwab Motion to Dismiss Decision, this Court held that the foregoing slide was "not protected by the [PSLRA] Safe Harbor" and is "actionable," because "when discussing Ozanimod clinical data and the NDA filing, Smith was required to fully and truthfully discuss the results."

359. On October 26, 2017, Celgene issued a press release (the "October 26, 2017 Press Release"), which stated that "Celgene plans to submit a New Drug Application (NDA) to the FDA for Ozanimod in RMS by year-end."

360. The foregoing statement was materially false or misleading at the time it was made, including because (i) data from the Mass Balance Study had, by October 26, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

361. In its Class Action Motion to Dismiss Decision, this Court held that "in light of Celgene's discovery of the Metabolite and the FDA's guidance concerning metabolites, as well as specific alleged facts, Celgene's disclosure as to the NDA submission," *i.e.*, "that it would submit the NDA for Ozanimod by the end of 2017," "was materially incomplete and misleading." The Court also found that given "FDA guidance . . . employees at Celgene, including Defendants Tran and Martin, knew that additional testing was required in light of the Metabolite discovery and that

the [FDA] was not going to approve the NDA without the necessary Metabolite testing results." Further, the Court stated that "[t]o make the public disclosures the NDA legally accurate, Celgene was required to also disclose meaningful information as to the Metabolite vis-à-vis the NDA."

362. As alleged in the Class Action Complaint, consistent with Celgene's standard quarterly disclosure process, information was furnished for this statement by I&I, including the Ozanimod NDA team, which was fully aware of the metabolite. Defendants Smith, Curran, and Martin also had known about the metabolite for months, as of October 26, 2017. Smith, as President and COO of Celgene, reviewed this statement. Smith, pursuant to his responsibility and authority to act as an agent of Celgene in his role as President and COO of Celgene, including through the quarterly disclosure process, had ultimate authority as a matter of law over this statement through his review, approval, and ratification of the statement. Smith also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the statement after its issuance.

363. Analysts and the media again focused on Celgene's statements that it would submit Ozanimod for FDA approval by the end of 2017. In an October 26, 2017 report, BTIG Equity Research stated "We expect ozanimod to be approved for MS during 2H2018 (US NDA sub for MS YE2017)." The Dow Jones Institutional News reported in an October 26, 2017 article: "Celgene plans to submit a New Drug Application (NDA) to the FDA for ozanimod in RMS by year-end."

364. On October 28, 2017, Celgene held an investor event during the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis (the "October 28, 2017 MSParis Presentation"). During the October 28, 2017 MSParis Presentation, Defendant Martin stated: "[T]he RADIANCE study and the SUNBEAM study will form the basis

of our submission to the FDA and to [the] EMA. For the FDA, we are working hard as we speak to get ready to file by the end of the year."

365. The foregoing statement was materially false or misleading at the time it was made, including because (i) data from the Mass Balance Study had, by October 28, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

366. In its Class Action Motion to Dismiss Decision, this Court held the foregoing statement actionable because when the statement was made "Celgene had discovered the Metabolite, knew that additional testing was required, and that the Metabolite compromised the safety and efficacy profile of Ozanimod. In short, without the necessary Metabolite testing, the NDA was dead on arrival. The fact that Defendants told investors about the positive clinical study results but failed to disclose the Metabolite discovery was misleading. Because Defendants chose to make statements regarding the clinical data, they were required to fully and truthfully disclose the results."

367. During the October 28, 2017 MSParis Presentation, Defendant Smith stated:

> We announced positive top line data to ozanimod and SUNBEAM and RADIANCE earlier in the year, and we've been very anxiously awaiting, getting to this meeting and being in a position to really get in and dig in and talk about the data. We're tremendously thrilled with the data and satisfied and happy.
>
> So it's very, very exciting for us to be heading off in this new venture in neurology, but heading off with such an amazing, potential

> cornerstone product as ozanimod with what we think is a very, very, very positive data.
>
> Since we went and made the acquisition and we've just continued to get more excited and more excited as we've continued to have data and whether that data was in MS and pivotal data, you see data firming up long term in the Phase II data, Crohn's data coming in. The data around this asset is very, very solid, and it's really, really exciting.

368. The foregoing statement was materially false or misleading at the time it was made, including because (i) data from the Mass Balance Study had, by October 28, 2017, revealed the existence of a previously unknown Ozanimod metabolite; (ii) Celgene's existing Ozanimod data and studies were insufficient to support the filing of an NDA given the metabolite and the time required to complete the necessary studies, including Phase I studies, and to generate the required data made unreasonable that an NDA would be submitted by the end of 2017; and (iii) if Celgene submitted the NDA without the necessary metabolite data and studies, the FDA was likely to issue a Refusal to File.

369. In its Class Action Motion to Dismiss Decision, this Court held the foregoing statement actionable because when the statement was made "Celgene had discovered the Metabolite, knew that additional testing was required, and that the Metabolite compromised the safety and efficacy profile of Ozanimod. In short, without the necessary Metabolite testing, the NDA was dead on arrival. The fact that Defendants told investors about the positive clinical study results but failed to disclose the Metabolite discovery was misleading. Because Defendants chose to make statements regarding the clinical data, they were required to fully and truthfully disclose the results." The Court also found that although the foregoing statement "refer[red] to the Phase III data," it was "not limit[ed] to that information. Instead, Smith essentially referred to all data that Celgene had acquired concerning Ozanimod."

370. Analysts discussed Celgene's the October 28, 2017 MSParis Presentation. Oppenheimer stated: "Celgene has previously announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA, based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017."

371. Celgene submitted the Ozanimod NDA to the FDA in December 2017, notwithstanding that it omitted the Metabolite testing results demanded by the FDA in its communications with the Company.

372. On January 8, 2018, Celgene filed with the SEC a Form 8-K (the "January 8, 2018 8-K"). The January 8, 2018 8-K listed as one of its "2018 Expected Operational Milestones," the "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)."

373. The foregoing statement was false or misleading when it was made, including because (i) Defendants had discovered the metabolite prior to the submission of the NDA; (ii) the results from Celgene's nonclinical toxicology studies were deficient; and (iii) the necessary testing and studies regarding the metabolite, including the data required to validate the results of the Phase I studies, were not complete at the time Celgene submitted the NDA, and Celgene's failure to include these results rendered the NDA facially deficient, including because the FDA had already told Celgene that this data was required.

374. In its Class Action Motion to Dismiss Decision, this Court held the foregoing statement actionable because "[w]hile Celgene truthfully stated that it submitted the NDA, this representation was misleading because of Plaintiff's allegations that Celgene knowingly submitted a facially deficient NDA that failure to contain information specifically requested by the FDA. By

telling investors that it submitted the NDA, Defendants were required to disclose the known shortcomings of Celgene's submission."

375. As alleged in the Class Action Complaint, consistent with Celgene's corporate process for public disclosures, information regarding the January 8, 2018 8-K's clinical and product development matters was furnished by the I&I franchise, and reviewed by I&I President Defendant Curran.

376. Analysts reported on the January 8, 2018 8-K. J.P. Morgan stated in a January 8, 2018 report, that the "Key 2018 catalysts" included "potential approval of ozanimod in relapsing multiple sclerosis in 2018" and RBC Capital Markets stated in a report published the same day that "CELG confirmed they submitted an NDA for ozanimod in MS."

377. On January 25, 2018, Celgene filed with the SEC a Form 8-K (the "January 25, 2018 8-K"). The January 25, 2018 8-K stated that "a New Drug Application (NDA) was submitted with the FDA for Ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE™ Part B and SUNBEAM™ trials for evaluating Ozanimod in patients with RMS."

378. The foregoing statement was false or misleading when it was made, including because (i) Defendants had discovered the metabolite prior to the submission of the NDA; (ii) the results from Celgene's nonclinical toxicology studies were deficient; and (iii) the necessary testing and studies regarding the metabolite, including the data required to validate the results of the Phase I studies, were not complete at the time Celgene submitted the NDA, and Celgene's failure to include these results rendered the NDA facially deficient, including because the FDA had already told Celgene that this data was required.

379. In its Class Action Motion to Dismiss Decision, this Court held the foregoing statement actionable because "[w]hile Celgene truthfully stated that it submitted the NDA, this representation was misleading because of Plaintiff's allegations that Celgene knowingly submitted a facially deficient NDA that failure to contain information specifically requested by the FDA. By telling investors that it submitted the NDA, Defendants were required to disclose the known shortcomings of Celgene's submission."

380. As alleged in the Class Action Complaint, consistent with his role and responsibilities in Celgene's process surrounding public disclosures, Defendant Smith received and reviewed draft and proposed final versions of the January 25, 2018 8-K in the days immediately prior to its issuance. Smith, as President and COO of Celgene, reviewed the foregoing statement. Smith, pursuant to his responsibility and authority to act as an agent of Celgene in his role as President and COO of Celgene, had ultimate authority as a matter of law over the foregoing statement through his review, approval, and ratification of the foregoing statement. Smith also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the foregoing statement after its issuance.

381. Analysts reported on the January 25, 2018 8-K. In a report that same day, SunTrust Robinson Humphrey stated that "Other Late Stage Assets Also Progressing Swiftly," and specifically noted with respect to Ozanimod that "U.S. approval and launch in relapsing multiple sclerosis (RMS) expected in 4Q18 (following NDA filing in December 2017 . . .)."

382. On February 7, 2018, Celgene filed its annual report for 2017 with the SEC on Form 10-K (the "2017 Annual Report"). The 2017 Annual Report stated that "a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS based on data from the phase III trials evaluating ozanimod in patients with RMS." The 2017 Annual Report also included

a chart representing that the "Status" of Ozanimod for RMS was "Regulatory submission" and that Celgene "Entered current status" in the fourth quarter of 2017.

383. The foregoing statements were false or misleading when they were made, including because (i) Defendants had discovered the metabolite prior to the submission of the NDA; (ii) the results from Celgene's nonclinical toxicology studies were deficient; and (iii) the necessary testing and studies regarding the metabolite, including the data required to validate the results of the Phase I studies, were not complete at the time Celgene submitted the NDA, and Celgene's failure to include these results rendered the NDA facially deficient, including because the FDA had already told Celgene that this data was required.

384. In its Class Action Motion to Dismiss Decision, this Court held the foregoing statements actionable because "[w]hile Celgene truthfully stated that it submitted the NDA, this representation was misleading because of Plaintiff's allegations that Celgene knowingly submitted a facially deficient NDA that failure to contain information specifically requested by the FDA. By telling investors that it submitted the NDA, Defendants were required to disclose the known shortcomings of Celgene's submission."

385. As alleged in the Class Action Complaint, consistent with his role in Celgene's quarterly disclosure process, Defendant Smith received and reviewed at least one draft version of the 20178 Annual Report as it was prepared and finalized in the days before its publication to the market. Smith, as President and COO of Celgene, reviewed the foregoing statements. Smith, pursuant to his responsibility and authority to act as an agent of Celgene in his role as President and COO of Celgene, including through the quarterly disclosure process, had ultimate authority as a matter of law over the foregoing statements through his review, approval, and ratification of the

foregoing statements. Smith also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the foregoing statements after their issuance.

SUMMARY OF DEFENDANTS' SCIENTER

386. Plaintiffs repeat and reallege each and every paragraph contained above as if set forth herein.

387. The Individual Defendants acted with scienter with respect to the materially false and misleading statements of material fact set forth above because they knew, or at the very least recklessly disregarded, that those statements were false when made. As senior executives of Celgene during the relevant time period, their scienter is imputable to the Company. As this Court held in the Class Action Motion to Dismiss Decision, "the scienter of the Individual Defendants who made actionable statements, who are all corporate officers, is imputed to Defendant Celgene."

I. Summary of Scienter as to Otezla for Defendants Smith and Curran

388. Defendants Smith and Curran were repeatedly warned that Celgene's 2017 Otezla sales guidance could not be met and should be lowered. For example, as alleged in the Class Action Complaint, FE 7 repeatedly warned Defendant Smith that Celgene's strategy of offering deep discounts and rebates for Otezla was fatally flawed and rendered it "impossible" for the Company to achieve the 2017 Otezla guidance. As early as the Otezla launch, FE 7 informed Smith—who had the final say with regard to Otezla and Market Access decisions—that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net revenues going forward. FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. FE 7 also told Smith that Celgene should never "pay to play"—*i.e.*, offer rebates and deep discounts in exchange for market access—as that would prevent Celgene from maximizing its profits. In November or December of 2016,

FE 7 met with, among others, Curran and warned these executives again that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges.

389. Defendants Smith and Curran had access to Otezla sales data showing steady to flat sales from 2014 through 2017.

390. No later than the third quarter of 2016, Tessarolo communicated in weekly meetings with the IIEC, which included Defendants Smith and Curran, that the 2017 Otezla guidance could not be met. By the end of 2016, Tessarolo again warned the IIEC of the need to lower the 2017 Otezla sales guidance, but the IIEC insisted that the forecasts would not be changed.

391. As alleged in the Class Action Complaint, during presentations in the third and fourth quarters of 2016, FE 17 and his team informed the IIEC that the 2017 Otezla sales guidance could not be met. FE 17 recounted that "everyone knew that the actual stated forecast was not reasonable" and could not be met. In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. According to FE 17, Defendants refused to lower the Otezla guidance per his warnings and instead put pressure on the salespeople to hit the impossible numbers. FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla guidance. However, rather than heed Tessarolo's warning, Defendant Smith cut him off, stating that he had heard enough of the negative information.

392. The forecasting team was "told to change" the numbers (*i.e.*, the internal forecasts) by Smith and Curran to conceal the lack of growth.

393. As alleged in the Class Action Complaint, FE 18 indicated that the aggressive Otezla guidance did not account for the introduction of new drug competition and that CPMAC knew of, but ignored, this factor.

394. As alleged in the Class Action Complaint, FE 19 stated that in late 2016, when Defendant Smith was assessing the 2017 Otezla market access information that FE 19's team put together and setting the sales targets, the market did not support anything close to the 57% growth Defendants told the investing public. According to FE 19, there was no way Defendant Smith could have interpreted what his Market Access team was reporting and translated that into 57% sales growth for Otezla in 2017.

395. Curran received, discussed, and presented information that Otezla's total sales units, gross revenue, and net revenue far underperformed the 2017 Budget forecast for the first quarter of 2017, and that April sales, which were flat as against the 2017 Budget forecast, did not make up any ground from the unexpected sales miss in the first quarter.

396. Curran received, discussed, and presented information that the psoriasis and psoriatic arthritis markets contracted in the first quarter of 2017, and that Otezla's market share was flat or declining.

397. Curran received, discussed, and presented information that I&I had determined that the 2017 Budget assumptions for the growth of the overall psoriasis and psoriatic arthritis markets, was flawed. Curran received, discussed, and presented information that the 2017 Budget assumptions for Otezla's shares of the psoriasis and psoriatic arthritis markets were also flawed.

398. Curran received numerous presentations and reports throughout the second quarter of 2017 indicating that Otezla's market share was either flat or declining throughout the second quarter of 2017.

399. A May 9, 2017 presentation submitted to Curran and other Celgene executives stated that Otezla's new patient growth—"new patients and not the NRx"—was "down" following

the launch of new competitors Taltz and Cosentyx, despite earlier 2017 Budget assumptions that IL 17 inhibitors, such as Taltz and Cosentyx, would have "no impact to Otezla."

400. On July 25, 2017, Curran recognized in an email that market share was "flat" versus the previous quarter. That same day, a member of Curran's team replied that Otezla's market share was "relatively flat"—which Curran herself repeated in a follow-up email to other Celgene executives. Despite this, Curran accepted false and misleading changes to a conference call script that she had drafted which stated that Otezla's market share "increased significantly" in the second quarter of 2017.

401. In its Class Action Motion to Dismiss Decision, this Court held that scienter was adequately pled as to Defendants Curran and Smith because they "received warnings from employees that Celgene's 2017 sales projections for Otezla was unattainable in approximately July 2016. Through FEs, Plaintiff provides sufficient circumstantial evidence to suggest that Curran's statement that Celgene was on-track to meet its 2017 goal was, at a minimum, recklessly made. . . . The temporal proximity of the statement at issue buttresses the Court's conclusion; Curran's statement was made after Otezla failed to meet Company expectations for the first quarter of 2017 and Celgene lowered the top end of the 2017 sales goal. Thus, the fact that Celgene was under pressure to find a new source of profitability gives rise to a strong inference of scienter that Curran was at best, recklessly disregarding the risk of misleading the public as to Celgene's ability to meet the Otezla sales projections."

II. Summary of Scienter as to Ozanimod for Defendants Smith and Martin

402. Upon acquiring Receptos, Celgene exercised control and decision-making authority over Receptos and Ozanimod. According to the Class Action Complaint, FE 2 recalled that Martin, who FE 2 described as a "control freak" and Smith's right-hand man, was sent by Celgene to San Diego to serve as the Managing Director for Receptos. FE 2 referred to Martin as

the de facto chief executive of Receptos. FE 5 likewise described Martin as the CEO of Receptos after the acquisition and confirmed that Martin was in charge of the entire Receptos organization and reported directly to Smith. FE 5 also recounted that Smith sent Gary Cline, Head of Strategic Research and Innovation, to San Diego to keep tabs on Ozanimod for him. FE 22 further corroborated that Martin reported directly to Smith and Saillot was Martin's second in command.

403. Martin knew that the belated Mass Balance Study posed significant risks to the publicly stated timeline for the Ozanimod NDA, which allowed "little time for delays/errors." During a January 12, 2017 meeting, the Ozanimod project team specifically discussed that "[i]f a significant new metabolite is identified, then we will not have sufficient toxicology to support the submission."

404. As alleged in the Class Action Complaint, based on a letter that Celgene received from the FDA on March 2, 2017 that was sent to Martin, any newly discovered metabolite would require full testing before an NDA was submitted, as reflected in a March 28, 2017 presentation stating that the "[c]urrent tox data package would not be sufficient if a new metabolite is identified."

405. According to the Class Action Complaint, FE 21 who had first-hand knowledge of the metabolite, discussed it with Martin and said it was of great concern. Martin told FE 21 not to tell anyone about the metabolite. FE 21 also stated that Celgene's senior leadership was briefed on the metabolite "quite some time before the filing" of the NDA.

406. As alleged in the Class Action Complaint, FE 5 recalled that during an Ozanimod meeting in March or April 2017, Tran confirmed the need for additional testing and studies of the metabolite. FE 5 confirmed that Martin was among the attendees at this meeting. FE 5 further

recalled that at this meeting Tran directed his comments concerning the metabolite to Martin and Saillot, but that Martin and Saillot quickly shut down the conversation

407. A presentation sent to Martin following a meeting on April 24, 2017 indicated the existence of the metabolite and the need for further testing per FDA guidance. The presentation acknowledged the possibility that Celgene would need to delay the NDA submission by up to eight months to perform the necessary testing.

408. On May 16, 2017, Saillot insisted that Martin explain to Smith the risks posed by the metabolite to the NDA submission, stating that "[i]n the best case scenario the December timeframe is extremely optimistic." On May 30, 2017, Tran echoed Saillot's concerns in an email to Saillot, stating that the additional testing that would be required on the metabolite "could have a significant negative impact on the NDA deliverables and timeline."

409. During a June 1, 2017 meeting of the Receptos Executive Committee, attended by Martin, the committee reviewed slides stating that the lack of sufficient long-term stability data was a "Primary concern" and that "Regulatory agencies will not consider data as validated due to lack of long-term stability (LTS) data." This concern was echoed in a presentation at a June 15, 2017 Ad Hoc Executive Committee meeting, which listed Martin as an invitee, which stated that "results are not considered validated due to lack of long-term stability data for PK samples at the time of filing [the NDA]." Martin also received a presentation on July 17, 2017 confirming that Celgene would not have the necessary long-term stability data at the time of the NDA submission.

410. In a July 25, 2017 email to Curran, which was forwarded to Smith, Martin stated that "FDA guidance on safety testing of metabolites (2016), metabolites present at disproportionately higher levels in humans than in any of the animal test species should be

considered for (non-clinical) safety assessment," and therefore "adequate characterization of Clinical Pharmacology properties of RP112273 is required by regulatory agencies."

411. As early as July 2017, Defendants recognized that if "Unaddressed [the discovery of the metabolite] would lead to a Refusal to File by FDA," as reflected in a July 17, 2017 draft Q&A document created for Martin.

412. Multiple senior Celgene employees working on the NDA, as well as Celgene's external consultants, acknowledged the severe deficiencies in the NDA.

413. Confirming that Defendants knew that the FDA could reject the Ozanimod NDA if all required testing was not completed before the submission, Curran agreed on November 20, 2017 that Celgene should consider pursuing a Priority Review Voucher if they "decide to wait until March-April 2018 to submit the NDA." This proposal was shared with Martin and Smith.

414. The FDA's Preliminary Meeting Comments, sent on November 21, 2017, which were reviewed by Martin and Smith, made clear that the metabolite testing results were required to be included in the Ozanimod NDA. Multiple employees within Celgene recognized that the FDA's Preliminary Meeting Comments meant that an RTF was nearly certain in the event Celgene proceeded with the NDA submission without the required testing of the metabolite.

415. In its Class Action Motion to Dismiss Decision, the Court found scienter adequately pled as to Smith and Martin with respect to Ozanimod. The Court held that:

> After Celgene discovered the Metabolite, Plaintiff pleads that at a minimum Tran and Martin knew by April 2017 of the Metabolite discovery and were aware that additional testing was necessary. FE 21 stated that Celgene's senior leadership was also aware of these facts, and FE 5 recounted that Martin reported to Smith. Given the importance of the product to Celgene, along with Martin's direct reporting responsibility to Smith, Plaintiff establishes a reasonable inference that Smith was also aware of the Metabolite. FE 21 also explained that he and his colleagues believed that if Celgene submitted the NDA without the Metabolite data, Celgene would

> receive an RFT. FE 21 "confirmed that this was said to his direct management," . . . who others have confirmed was Martin.
>
> The Court, therefore, concludes that the fact that Celgene was under pressure to find a new source of profitability gives rise to a strong inference that Smith and Martin were at best, recklessly disregarding the risk of misleading the public as to Celgene's ability to obtain FDA approval for Ozanimod.

III. Celgene's Scienter as to Ozanimod

416. The scienter of Celgene as to statements about Ozanimod may be found based on the number of high-ranking officials within Celgene who were aware of the metabolite and the inability of the Company to complete the required testing of the metabolite before the planned NDA submission date in December 2017. As alleged above, numerous senior Celgene employees—in addition to Defendants Smith, Curran, and Martin, who directly participated in the review and approval of Celgene's corporate statements and/or provided information for inclusion in those statements—were responsible for drafting, reviewing, and approving portions of the Ozanimod NDA. These senior Celgene employees knew of undisclosed material facts that made Celgene's public statements about the Ozanimod NDA materially false or misleading, including the existence of the metabolite and the need for additional testing of the metabolite before the Ozanimod NDA could be submitted. The extensive involvement of these employees and Defendants Smith, Curran, and Martin in the Ozanimod NDA process demonstrates that Defendants' fraud was sufficiently widespread and egregious and rendered Celgene's public statements about the Ozanimod NDA blatantly false, so as to infer Celgene's corporate scienter, even apart from any imputation via Defendants Smith, Curran, and Martin.

PRESUMPTION OF RELIANCE

417. Plaintiffs intend to rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things: (a) Defendants made public misrepresentations

or failed to disclose material facts during the relevant time period; (b) the omissions and misrepresentations were material; (c) Celgene common stock traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Celgene common stock; and (e) Plaintiffs purchased Celgene common stock between the time Defendants misrepresented or failed to disclose material facts and the time when the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

418. The market for Celgene common stock was open, well-developed and efficient at all relevant times. As a result of the aforementioned materially false and misleading statements, Celgene common stock traded at artificially inflated prices during the relevant period. The artificial inflation continued until the time the market fully came to realize the nature and extent of Defendants' misrepresentations concerning Otezla and Ozanimod and/or the consequence of the undisclosed risks concealed by those misrepresentations fully materialized.

419. At all relevant times, the market for Celgene common stock was efficient for the following reasons, among others: (a) Celgene filed periodic reports with the SEC; (b) Celgene common stock was listed and actively traded on the NASDAQ during the time that Plaintiffs purchased Celgene common stock; (c) numerous analysts followed Celgene; and (d) Celgene regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

420. In its Class Action Certification Decision, this Court held that "Celgene stock traded in an efficient market." The Court also held that "Defendants failed to rebut the *Basic* presumption of reliance."

421. Plaintiffs relied on the market price of Celgene common stock, which reflected all the information in the market, including the misstatements by Defendants.

PLAINTIFFS' ACTUAL RELIANCE

422. During the relevant period, Plaintiffs' investment in Celgene common stock was managed by HealthCor. HealthCor made the investment decisions with respect to Plaintiffs' purchases of Celgene common stock and Plaintiffs' decision to continue to hold and not dispose of Celgene common stock. Factors considered by Celgene in making such decisions included, among other things, Celgene's drug portfolio and pipeline and a review of the Company's strengths, weaknesses and opportunities.

423. Prior to making the decision to purchase Celgene common stock, a Healthcor investment professional actually and justifiably read, reviewed and relied upon (to the extent the referenced documents had been published at the time) the September 12, 2016 Presentation, April 27, 2017 Earnings Call, July 27, 2017 Earnings Call, July 27, 2017 8-K, Cantor Fitzgerald Presentation, October 26, 2017 Earnings Call, October 26, 2017 Press Release, October 28, 2017 MSParis Presentation, January 8, 2018 8-K, January 25, 2018 8-K, and 2017 Annual Report including (as applicable): (a) the statements about Otezla's market share, new prescriptions, sales, and 2017 sales guidance; and (b) the statements about the intended December 2017 filing with the FDA of the NDA for Ozanimod (and the filing of that NDA once it occurred).

424. Defendants' statements concerning Otezla's market share, new prescriptions, sales, and 2017 sales guidance and the intended December 2017 filing with the FDA of the NDA for Ozanimod (and the filing of that NDA once it occurred) were material to HealthCor's decision to purchase (and hold) Celgene common stock on Plaintiffs' behalf. Both Otezla and Ozanimod were promised by Celgene to be drugs that could make up the revenue provided by Revlimid once that drug went off-patent in 2022. Given that Revlimid accounted for a majority of Celgene's net sales

revenue, the ability of Celgene to replace Revlimid revenue was material to HealthCor in evaluating whether to purchase (and hold) Celgene common stock.

425. HealthCor actually and justifiably relied upon information contained in Celgene's (to the extent each such document was on file with the SEC or publicly available at the time) in making each purchase of Celgene common stock on behalf of Plaintiffs and in choosing to hold and not dispose of, Celgene common stock.

LOSS CAUSATION

426. As the truth about Otezla's sales and the deficient Ozanimod NDA entered the market and/or the risks concealed by Defendants' misrepresentations about those subjects materialized, the price of Celgene common stock dropped.

427. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs. During the time that Plaintiffs purchased Celgene common stock, or made an investment decision to hold that stock, the market price of those securities was artificially inflated as a direct result of Defendants' materially false and misleading statements. Specifically, Celgene's misrepresentations about Otezla and Ozanimod caused the price of Celgene's common stock to be artificially inflated.

428. As a series of disclosures was issued correcting (or partially correcting) the prior false and misleading statements with respect to Otezla and Ozanimod and/or the risks concealed by Defendants' misrepresentations about those drugs materialized, the price of Celgene common stock declined precipitously, and Plaintiffs were damaged.

429. On October 26, 2017, Celgene released its third quarter 2017 financial results. Celgene reported total Otezla sales of only $308 million, a 14% decline from second quarter 2017 sales. Defendant Curran stated that Otezla experienced "lower-than-expected revenue due to market deceleration, increase in gross-to-net discounts to drive biologic step free access and

inventory fluctuation." In addition, Curran referenced Otezla's depressed market share, which "has been somewhat impacted in patients previously exposed to biologics." Curran also stated that "declined script volume became more prominent" in the third quarter of 2017. According to Curran, declining script volume, combined with "the market's softening, increased competition, as well as the impact from GTN" (gross to net) led to disappointing third quarter of 2017 results.

430. Celgene also reduced its 2017 guidance for Otezla sales from between $1.5 billion and $1.7 billion to approximately $1.25 billion. Celgene also lowered its fiscal 2020 guidance as a result of the poor Otezla results.

431. At the close of trading on October 26, 2017, Celgene common stock closed at a price of $99.99 per share, down from a price of $119.56 per share at the close of trading on October 25, 2017. This was a decline of $19.57 per share, or more than 16%.

432. This decline in Celgene's common stock price was a result of the correction of Celgene's misrepresentations about Otezla's sales, market share, and 2017 net sales forecast and/or resulted from the materialization of risks about those subjects concealed by Defendants' misrepresentations.

433. Analysts commented negatively not only on Celgene's missed and lowered guidance, but also on management's credibility. J.P. Morgan reported on October 26, 2017 that Celgene "management faces a major credibility issue." That day, Cowen and Company similarly reported that the shortfall on Otezla sales "is likely to impact the company's credibility." On October 26, 2017, *SeekingAlpha* also reported that "the Street has suddenly lost trust in Celgene's pipeline as well as the credibility of management's guidance."

434. Raymond James downgraded Celgene and wrote:

> [T]oday's update substantially alters our outlook and confidence in the company's ability to execute. We previously viewed Celgene's

> immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-0301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a 'show me' story.

435. BTIG Equity Research reported on October 26, 2017 that Celgene's third quarter results "severely disappointed relative to expectations on Otezla, and mgmt significantly lowered 2020 guidance due to several product forecast revisions." Jefferies Group LLC also reported that day that "CELG put up an unusual notable revenue miss (it's been a few years since that happened by this much) and notably lowered 2017 revenue guidance and 2020 revenue and EPS guidance," and that "it will take some time to re-engage in credibility to hit targets and get quarters back on track and reset the situation."

436. Analysts also discussed the factors that drove Celgene's lower Otezla revenues. For example, in an October 26, 2017 report, BMO Capital Markets attributed the Otezla miss in part to discounting and competition from other drugs, stating that "[a]lthough Otezla script growth was apparent (+4% Q/Q), it just wasn't enough to offset the aggressive discounting and slowing growth of psoriatic arthritis and greater competition in psoriasis markets."

437. Despite Celgene's disclosure about Otezla's disappointing sales and lowered guidance, and the resultant stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to misrepresent and hide from the investing public the truth about Ozanimod.

438. On February 27, 2018, after market close, Celgene disclosed that it had received a Refuse to File letter from the FDA regarding its NDA for Ozanimod. Celgene stated: "[U]pon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate

guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA."

439. At the close of trading on February 28, 2018, Celgene common stock closed at a price of $87.12 per share, down from a price of $95.78 per share at the close of trading on February 27, 2018. This was a decline of $8.66 per share, or more than 9%.

440. This decline in Celgene's common stock price was a result of the partial correction of Celgene's misrepresentations about the Ozanimod NDA and/or resulted from the partial materialization of risks about that subject concealed by Defendants' misrepresentations.

441. On February 27, 2018, Raymond James reported that the market "didn't see this one coming," and called the new RTF news an "unexpected development." *SeekingAlpha* reported the same day that the news of Celgene's RTF was "hard to accept as a reality" because receiving such a refusal to file letter from the FDA is "almost unheard of for a major company." Credit Suisse similarly expressed disappointment and surprise, noting that "we are disappointed by the timing delay related to the filing, and we think that this will continue to further concerns associated with management execution."

442. RBC Capital Markets reported on February 27, 2018 that "given that [Celgene] will be requesting a Type A meeting with the FDA, it may be some time before there is additional clarity on the potential path forward. We view ozanimod as one of the most, if not the most, important pipeline programs for CELG."

443. Despite Celgene's disclosure of the RTF and the related stock-price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal material information about the testing required to address the metabolite and how that testing would affect the timeline for submitting a revised NDA. This concealment also served to forestall

the full materialization of the risks concealed by Defendants' misrepresentations about the Ozanimod NDA.

444. On Sunday, April 29, 2018, Morgan Stanley issued a strongly negative report based on its detailed review of certain obscure data related to Ozanimod's other metabolites. Morgan Stanley's April 29, 2018 report entitled, "More Bread Crumbs Yield Less Confidence in Ozanimod," stated that its "analysis of prior ozanimod pre-clinical studies suggest [that] CC112273 concentrations in prior pre-clinical work is unlikely to approximate human clinical doses" and, "[t]herefore we believe it is increasingly likely mgt. will need to complete new preclinical work on CC112273 ***setting up a 1 to 3 year delay***."

445. The Morgan Stanley analysis involved significant investigation beyond regurgitating existing news. The Morgan Stanley analysts explained that their analysis was only made possible after they "were able to locate copies of [] posters over the weekend [April 28 and 29]" containing the "previously published ozanimod preclinical toxicology results and studies of [the two] known metabolites," *i.e.*, other than CC112273. The posters established that the two previously identified metabolites produced levels in the animal studies that were just above the human therapeutic dose and therefore approximated the human dose. The analysts further explained that, based on their review of FDA guidance on metabolites, "the only way for mgt. to avoid synthesizing CC112273 and re-running preclinical toxicology was by having exposure of CC112273 in animals equivalent to the human therapeutic dose" so that Celgene could simply recycle the prior testing used on the known metabolites. However, as Morgan Stanley explained, a "1 to 3 year delay" in completing the requisite testing was unavoidable given the significantly higher levels of the Metabolite in humans compared to animals. Morgan Stanley referred to its "prior review of FDA guidance on metabolites" and stressed that:

> However, given that mgt. indicated 'CC112273 levels were ***much lower*** . . . in the animal species used in the non-clinical studies than the amount produced by humans' and that ***our calculations suggest the prior set of identified (and thus studied metabolites) produced levels barely above the human therapeutic dose, we believe it is increasingly unlikely CC112273 produced levels near the human therapeutic dose in the prior preclinical work. Thus, mgt. will likely need to re-run preclinical toxicology which could take 6 months (rats) to 2 years (another carcinogenicity study). Given the timeline to start the study, produce the study reports and refile, we believe the delay is at a minimum 1 year and up to 3 years if mgt. must redo all animal work.***

446. At the close of trading on April 30, 2018, Celgene common stock closed at a price of $87.10 per share, down from a price of $91.18 per share at the close of trading on April 27, 2018. This was a decline of $4.08 per share, or about 4.5%.

447. This decline in Celgene's common stock price was a result of the correction of Celgene's misrepresentations about the Ozanimod NDA through the Morgan Stanley report (*i.e.*, the length of the likely delay before Celgene could resubmit the Ozanimod NDA to the FDA) and/or resulted from the materialization of risks about that subject concealed by Defendants' misrepresentations.

448. Analysts linked the decline in Celgene's common stock price to the Morgan Stanley report. *The Motley Fool* wrote on April 30, 2018 that: "[S]hares of Celgene lost 4.5%. The biotech giant got negative comments from analysts at Morgan Stanley, who predicted that it could take several years for Celgene to move forward with plans to file for approval from the U.S. Food and Drug Administration for its multiple sclerosis candidate drug ozanimod." Similarly, *Citywire* reported on the same day that "Celgene shares fell 4.5% after Morgan Stanley said it expects a delay of up to three years for Celgene's key multiple sclerosis drug, ozanimod." Likewise, *Marketwatch* also reported on April 30, 2018 that "Celgene Corp. . . . fell 4.5% after a Morgan

Stanley report predicted a one- to three-year delay on any new attempt to file for U.S. approval of the company's highly anticipated drug ozanimod, which is designed to treat multiple sclerosis."

449. The Morgan Stanley report also materialized the concealed risk of the metabolite information. With lost trust in management, reasonable investors would be expected to attempt to predict the length of time a new approval would take. The Morgan Stanley report, with extensive investigation and analysis, provided a value relevant prediction contrary to management's prior representations, materializing the risk of management's failure to fully and properly disclose the metabolite earlier.

NO SAFE HARBOR

450. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not "forward-looking statements" nor were they identified as "forward-looking statements" when made. Nor was it stated with respect to any of the statements forming the basis of this Complaint that actual results "could differ materially from those projected." To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Celgene who knew that those statements were false when made.

451. As alleged herein, in the Class Action Motion to Dismiss, the Class Action Certification Decision, and the Schwab Motion to Dismiss Decision, the Court has already

determined that the statutory safe harbor does not apply to many of the allegedly false statements pleaded in this Complaint.

FIRST CAUSE OF ACTION

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

452. Plaintiffs repeat and reallege each and every paragraph contained above as if set forth herein.

453. This cause of action is brought against Defendants Celgene, Curran, Martin, and Smith for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j, and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, based on misrepresentations made from April 27, 2017 through February 7, 2018.

454. Defendants Celgene, Curran, Martin, and Smith both directly and indirectly used the means and instrumentalities of interstate commerce in the United States to make the materially false and misleading statements and omissions of material fact alleged herein to: (i) deceive the investing public, including Plaintiffs, as alleged herein; (ii) artificially inflate and maintain the market price of Celgene common stock; and (iii) cause Plaintiffs to purchase Celgene common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Celgene, Curran, Martin, and Smith took the actions set forth above.

455. Defendants Celgene, Curran, Martin, and Smith both directly and indirectly: (i) employed devices, schemes and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Celgene common stock in an effort to artificially inflate and maintain the market

prices for Celgene common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5.

456. By virtue of their high-level positions at the Company, Curran, Martin, and Smith were authorized to make public statements, and made public statements on Celgene's behalf. These senior executives were privy to and participated in the creation, development, and issuance of the materially false and misleading statements alleged herein, and/or were aware of the Company's and their own dissemination of information to the investing public that they recklessly disregarded was materially false and misleading.

457. In addition, Celgene, Curran, Martin, and Smith had a duty to disclose truthful information necessary to render their affirmative statements not materially misleading so that the market price of the Company's securities would be based on truthful, complete and accurate information.

458. Defendants Celgene, Curran, Martin, and Smith acted with knowledge or reckless disregard for the truth of the misrepresented and omitted facts alleged herein, in that they failed to ascertain and disclose the facts, even though such facts were known or readily available to them. The material misrepresentations and omissions made by Defendants Celgene, Curran, Martin, and Smith were done knowingly and/or recklessly, and had the effect of concealing the truth with respect to Celgene's operations, business, performance, and prospects from the investing public, including misrepresenting and concealing (i) the current state of Otezla's sales and the drug's ability to gain market acceptance, capture market share, and generate revenue for Celgene, including to achieve the Company's 2017 forecast for the drug; and (ii) the undisclosed discovery of a key, active metabolite of Ozanimod that required further testing, the sufficiency of that testing data, and the completeness of Ozanimod's application for FDA approval as a treatment for multiple

sclerosis. By mispresenting and concealing these material facts from investors, Celgene, Curran, Martin, and Smith supported the artificially inflated price of Celgene's common stock.

459. The dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, artificially inflated the market price of Celgene's common stock. In ignorance of the fact that the market prices were artificially inflated, and relying directly or indirectly upon the materially false and misleading statements made by Defendants, and upon the integrity of the market in which the Company's securities trade, or upon the absence of material adverse information that was recklessly disregarded by Defendants, but not disclosed in public statements by Defendants, Plaintiffs purchased Celgene common stock at artificially inflated prices. As a series of partial but inadequate disclosures were issued (or concealed risks materialized), the price of Celgene's securities substantially declined.

460. At the time of the material misrepresentations alleged herein, Plaintiffs were ignorant of their falsity, and believed them to be true. Had Plaintiffs known the truth with respect to the business, operations, performance and prospects of Celgene, which was concealed by Defendants, Plaintiffs would not have purchased Celgene common stock, or if they had purchased such securities, they would not have done so at the artificially inflated prices that they paid.

461. By virtue of the foregoing, Defendants Celgene, Curran, Martin, and Smith have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

462. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages in connection with their transactions in the Company's securities.

463. Taking into account, *inter alia*, tolling of the limitations period by the filing of the Class Action, Plaintiffs have brought their Exchange Act claims within two years of discovery of

the violations alleged herein, and within five years of the violations alleged herein. Consequently, Plaintiffs' Exchange Act claims are timely.

SECOND CAUSE OF ACTION

Common Law Fraud
Against All Defendants

464. Plaintiffs repeat and reallege each and every paragraph contained above as if set forth herein.

465. As alleged above, Defendants Celgene, Curran, Martin, and Smith made material misrepresentations of material fact as set forth above.

466. These misrepresentations were made intentionally, or at a minimum, recklessly, to induce reliance thereon by Plaintiffs when making decisions to invest in Celgene common stock or to continue holding (*i.e.*, refrain from disposing of) Celgene common stock.

467. These misrepresentations constitute fraud and deceit under the common law.

468. Plaintiffs actually, reasonably, and justifiably relied upon the representations when making decisions to purchase Celgene's common stock, or to hold (*i.e.*, refrain from disposing of) Celgene common stock, and did not know of any of the misrepresentations or omissions.

469. As a direct and proximate result of the fraud and deceit by Defendants Celgene, Curran, Martin, and Smith, Plaintiffs suffered damages in connection with their investment in Celgene common stock (including their decision to hold Celgene common stock).

470. Defendants' wrongful conduct, as described above, was malicious, reckless, willful, and was directed at the general investing public. Accordingly, punitive damages, in addition to compensatory damages, are appropriate to deter fraudulent conduct of this kind.

471. Taking into account, *inter alia*, tolling of the limitations period by the filing of the Class Action, Plaintiffs' common law fraud claim is timely.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request relief and judgment, as follows:

(a) Awarding compensatory damages against Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;

(b) Awarding punitive damages against Defendants;

(c) Awarding Plaintiffs their reasonable costs and expenses incurred in this action; and

(d) Such other and further relief as the Court may deem just and proper.

JURY DEMAND

The Plaintiffs hereby demand a trial by jury as to all issues so triable.

Dated: April 26, 2022
New York, New York

ROLNICK KRAMER SADIGHI LLP

By: *s/ Lawrence M. Rolnick*

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